EXHIBIT DX2

TO DECLARATION OF
DEBORAH E. LEWIS IN SUPPORT
OF DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTION
TO EXCLUDE TESTIMONY OF
ALEXANDER A. HANNENBERG, M.D.

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- - - - - - - - - - - - - - - - - -

In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

- - - - - - - - - - - - - - - - - -

DEPOSITION OF ALEXANDER A. HANNENBERG

VOLUME I, PAGES 1 - 306

AUGUST 8, 2017

(The following is the deposition of ALEXANDER A. HANNENBERG, taken pursuant to Notice of Taking Deposition, via videotape, at the Aloft Boston Seaport Hotel, 401-403 D Street, Boston, Massachusetts, commencing at approximately 9:16 o'clock a.m., August 8, 2017.)

APPEARANCES:
On Behalf of the Plaintiffs:
Gabriel Assaad
KENNEDY HODGES
4409 Montrose Boulevard, Suite 200
Houston, Texas 77006

Genevieve M. Zimmerman
MESHBESHER & SPENCE, LTD.
1616 Park Avenue
Minneapolis, Minnesota 55404

On Behalf of Defendants:
Deborah Lewis
BLACKWELL BURKE P.A.
431 South Seventh Street, Suite 2500
Minneapolis, Minnesota 55415

ALSO APPEARING:

Ronald M. Huber, Video Technician

I N D E X

P R O C E E D I N G S

(Witness sworn.)

ALEXANDER A. HANNENBERG

called as a witness, being first duly sworn, was examined and testified as follows:

ADVERSE EXAMINATION

BY MR. ASSAAD:

Q. Please state your name.

A. Alexander Hannenberg.

Q. You may need to speak up a little bit.

A. Okay.

Q. My name's Gabriel Assaad and I represent thousands of plaintiffs in the multidistrict litigation. I'm here to ask you numerous questions regarding your expert opinions today. Do you understand that?

A. Yes, I do.

Q. Okay. Have you had your deposition taken before?

A. Yes.

Q. Approximately how many times?

A. Once.

Q. And was that a medical malpractice case?

A. It was.

Q. And what were the allegations in that case?

A. The allegations were negligent care by the anesthesiologist in the postoperative demise of a surgical patient.
Q. And were you an expert for the plaintiff or the defendant?
A. I was an expert for the defense.
Q. Okay. And did you know the doctor that was --
A. No.
Q. -- who the lawsuit was filed against?
A. No.
Q. I'm --
Let me go through the instructions real quick. This is your second time doing a deposition and I may do things differently than what was before, but I'm going to ask you numerous questions. If you don't understand my question, please let me know. Fair?
A. Yes.
Q. Okay. Please answer in the affirmative, "yes" or "no." Shaking your head is something difficult for the court reporter to take down and we need a -- a complete and accurate transcript. Do you understand?
A. I do.

Q. If you do answer the question that I ask, I'm going to assume that you understood the question. Fair?
A. Yes.
Q. And please don't answer any questions unless you understand them. Fair?
A. Yes.
Q. Okay. Any time you want to take a break, that is fine; I just ask that if there's a pending question, you ask for a break after you answer the question. Fair?
A. Understood.
Q. What was the outcome of that medical malpractice case, if you know?
A. It was settled.
Q. Okay. Do you know for how much?
A. I don't.
Q. Okay. Where was it located?
A. Hartford, Connecticut.
Q. And do you recall the name of the attorney that hired you?
A. No, I don't.
Q. How long ago was this?
A. Three or four years -- three or four years ago.

Q. And how was it you became involved in that medical malpractice case?
A. I received a phone call from a law firm briefly describing the circumstances of the case and asking whether I would review the material.
Q. Okay. Do you advertise for expert services?
A. No.
Q. Do you know how they got your name?
A. I don't.
Q. Okay. Do you know how you got involved in this case?
A. Sort of a similar scena -- scenario. I received a -- a phone call originally asking about one of the single cases and asking whether I would review it and offer an opinion.
Q. Okay. Do you know who contacted you?
A. That would have been Greenberg Traurig.
Q. Okay. Do you know who at Greenberg Traurig?
A. I can't recall -- recall, but I'm close.
Q. Male or female?
A. Male.
Q. Evan Holden?
A. Yes.
Q. Okay. Do you consult for 3M?
A. Do I con --

No, only -- only in this matter, in which case I guess I consult for the law firm.
Q. Do you -- do you know anyone at -- that works for 3M?
A. I don't believe so, no.
Q. Okay.
(Exhibit 1 was marked for identification.)
BY MR. ASSAAD:
Q. Have you ever been --
Before I talk about Exhibit 1, have you ever been -- or done any research that was funded by 3M?
A. No.
Q. Okay. Do you know Scott Augustine?
A. I have met him.
Q. How long ago?
A. More than five years ago.
Q. Okay. You just met him once?
A. I believe so.
Q. Did you have a conversation with him?
A. Yes.
Q. And what was the conversation about?
A. It was about the content of a scientific panel at the anesthesia annual meeting at which I had presented. He approached me at the end of the -- end

of the session to comm -- comment on the -- on -- on the session. Exactly his point I don't -- I don't recall.
Q. What was your presentation on?
A. It was about performance measurement relative to intraoperative temperature management.
Q. Okay. And I believe that's on your curriculum vitae; correct?
A. Yes.
Q. So if I want to know the date of that -- I think you gave one or -- one talk on that; correct?
A. On -- on that particular performance measure, yes, I think just one.
Q. Yeah. Okay. So that if I look at your CV, that would be about the time you spoke with Dr. Scott Augustine.
A. Yes.
Q. And did you ever speak with him again?
A. No.
Q. Okay. What's been marked as Exhibit 1 is what you produced, attached to your expert report on June 2nd, 2017. Can you please look at Exhibit 1 and let me know if that's what was attached to your expert report on June 2nd, 2017.

A. Yes, --
Q. Okay.
A. -- it is.
Q. At the time that you submitted your expert report on June 2nd, 2017, were all the -- were all those items listed on Exhibit 1 all the materials you considered in formulating your opinions?
A. No. That's why I submitted a revised document.
Q. Okay. So are you saying that Exhibit 1 was incorrect at the time you submitted it --
A. Yes.
Q. -- to the -- Let me finish my question.
A. Uh-huh.
Q. You have to let me finish my question because the court reporter --
A. Okay.
Q. -- will stop this whole deposition at yell at me.
MS. ZIMMERMAN: It's happened before.
Q. So at the time of submitting Exhibit 1 on June 2nd, 2017, the -- regarding the materials you considered for your -- to formulate your expert opinions, are you saying at the time it was

incomplete?
A. Yes, I did.
Q. Okay.
(Exhibit 2 was marked for identification.)
BY MR. ASSAAD:
Q. I'm still on Exhibit 1. With respect to Exhibit 1, are all the materials that you considered, do you consider them authoritative?
A. What do you mean by "authoritative?"
Q. Reliable.
A. No. There are -- there are some items in this report who -- that offers conclusions I'm not sure are valid.
Q. Okay. This is just stuff that you've considered; correct?
A. Yes.
Q. And is this -- And what's been marked as Exhibit 2 is a document that was provided to plaintiffs' counsel this morning that is titled "Materials Considered;" correct?
A. Yes.
Q. Okay. And this is different than Exhibit 1; correct?

A. Yes.
Q. What is different?
A. There are four -- four or five publications that are on Exhibit 2 that aren't on Exhibit 1.
Q. And it's my understanding today that you considered those publications at the time of submitting your expert report, you just failed to include them on the Materials Considered; is that correct?
A. Yes, sir.
Q. Okay. And the five publications are what?
A. Let's see, Legg, Wood, Melling, Scott. I think those are the -- I think those are the additions.
Q. Okay. Now when did you create Exhibit No. 2?
A. Yesterday.
Q. Yesterday. Why did you create -- What made you decide to look at what materials were considered and revise Exhibit 1 to create Exhibit 2?
A. In -- in thinking about today's session I realized that there were items that I had, over an extended period of time, considered in thinking about this matter that weren't originally listed.

Q. Okay. Is it fair to say that these four items, which are Legg, Wood, Melling and Scott, are not cited in your expert report?
A. It's easy enough to check if I can see my expert report.
(Exhibit 3 was marked for identification.)
A. That is correct, they are not cited.
Q. Okay. You've been asked to be an expert in this case; correct?
A. Yes.
Q. And you agree that an expert should be -- should be objective; correct?
A. Yes.
Q. Should not be an advocate for either side; correct?
A. Yes.
Q. Should be accurate; --
A. Yes.
Q. -- correct?
So I'm trying to understand what was it yesterday that made you think of these four documents.
A. I was ref -- reflecting on the conversation that we were going to have today and realized that my thinking about the matter at hand was informed by

material other than those that were on the Materials Considered list.
Q. Okay. Did you review any depositions?
A. Did I --
Yes, I reviewed depositions.
Q. That's not on Exhibit 2; correct?
A. That is on --
I'm sorry, I -- I -- I stand corrected. The expert reports.
Q. So you haven't looked at any depositions?
A. Have I looked at any dep --
Hon -- honestly, to make a distinction between the depositions and the expert reports, I'm not totally clear on --
Q. You don't know what a deposition is?
A. I know what a deposition is, but when I think -- think about the opinions of those who have been deposed and those who have submitted expert reports, in my mind I'm not clear on in what format I considered the material from those individuals.
Q. So sitting here today you don't know what depositions you reviewed, if any.
A. I believe I have reviewed depositions. Which ones, and which ones I relied on the expert reports, I'm not able to say.

Q. Well on Exhibit 2 you only have two expert reports of Dr. Michael J. Stonnington and Dr. William Jarvis; correct?
A. Yes.
Q. Did you review any other expert reports?
A. Yes, I'm -- I'm sure I did.
Q. Which ones?
A. Dr. Wenzel and Dr. Kuehn or Keen.
Q. Which one, Kuehn, Keen, or both?
A. I don't know. I'd have to look at -- look at them to see.
Q. Was it -- was it a University of Minnesota professor or a person from Toronto?
A. I -- I have no idea.
Q. Okay. Do you have that with you today?
A. No, I don't.
Q. Okay. What other expert reports?
A. I can't think of any others.
Q. What about Borak, does that sound familiar?
A. No.
Q. Holford?
A. No.
Q. Mont?
A. Mont, per -- perhaps. The name sounds fam -- familiar. Whether it's a paper or deposition

or an expert report I'm not sure, but the name --
Q. Houge?
A. No.
Q. Abraham?
A. It doesn't sound familiar.
Q. Did you see any videos regarding airflow?
A. I --
Yes, I have.
Q. Okay. And what -- what do you recall?
A. I -- I recall -- I recall that the video depicted a study of airflow in essentially a vacant operating room.
Q. Okay. So there was no individuals in that airflow video; correct?
A. Correct. Or there was a single mannequin -- mannequin. My conclusion from looking at it was that it was a contrived model of an operating room.
Q. Okay. How did you obtain that video?
A. I'm not -- I'm not sure whether it was among the materials that was e-mailed to me along with many other clinicians, or whether it was something that was provided by -- by counsel.
Q. Did you consider that in formulating your opinions?
A. Only to the extent I just -- I just stated,

that I didn't think that it offered any credible evidence about operating room airflow in a vacant operating room without any live personnel or activity or equipment.
Q. But you considered it; correct?
A. Yes.
Q. Why isn't it on Exhibit 2?
A. It was an omission.
Q. Any other omissions in Exhibit 2 that you can think of?
A. Not -- not that I can think of.
Q. Okay. Did you look at Hughes' report?
A. I don't believe so.
Q. Lampotang?
A. No.
Q. Ulatowski?
A. No.
Q. Settles?
A. No.
Q. Okay. So my understanding is the only expert reports you've seen are Dr. Wenzel, Dr. Kuehn, Dr. Mont.
A. That is the best of my recollection.
Q. On the defense side; correct?
A. I don't know whether those are on the

defense -- defense side, but those are the reports.
Q. And as well as the two reports listed in Exhibit 2; correct?
A. Yes.
Q. Okay. Let's talk about depositions. Have you --
You know what a deposition transcript looks like; correct?
A. Yes.
Q. I mean you've been deposed before and I'm sure you reviewed your deposition transcript; correct?
A. Correct.
Q. There's someone asking questions and there's the deponent answering the questions; correct?
A. Yes.
Q. Okay. I just want to be clear that you understand what it is before I ask you the next question. So you're clear you understand what a deposition is.
A. Yes.
Q. Okay. Do you recall reading any such documents in the past, you know, in -- in -- in this case?
A. Yes.
Q. Which -- which ones?

A. I don't know.
Q. You don't know.
A. I don't -- I -- I -- I don't know. As I said, the -- my impression -- my impressions are related to the content, not so much the format; that is to say, if an individual is deposed and offered an expert opinion, whether I reviewed their expert opinion or the deposition is hazy in my mind as I sit here today.
Q. Let's -- maybe we can make it sim -- be simplified. Did you rely on anything you read in the depositions in formulating your opinions?
A. That -- that is possible.
Q. Well I don't want "possible," I want to know one way or the other.
A. Okay. I am unable to tell -- to tell you what I was --
What I've been saying is that I've reviewed materials in various -- in various formats from various sources. My -- whatever opinion I hold -- hold today is the result of the sum of that information, and I have not really made an effort to connect an opinion with whether it is directly derived from a particular document.
Q. So if I understand --

A. My --
Q. -- you today, that with respect to your opinions, you don't know all the materials that you're using to rely upon in formulating those opinions; is that correct?
MS. LEWIS: Object to the form.
A. I am relying on a variety of materials and my clinical training and experience to form my opinion.
Q. I understand that. But besides what's been marked as Exhibit 2 and the three expert reports that we've mentioned, Wenzel, Kuehn and Mont, as well as the Abraham video, sitting here today you cannot testify as to what other documents or materials you used and relied upon to formulate your opinions; is that correct?
A. That's correct.
MS. LEWIS: Objection, form.
MR. ASSAAD: Basis.
MS. LEWIS: Misstating the -- his testimony. He didn't say whether it was Abraham's video or whose video, he just said video.
MR. ASSAAD: Okay. You may answer.
A. Yeah. I clar -- was about to say the same thing.

Q. Let me ask the question again then, get it nice and clean.
My understanding is what's been marked as Exhibit 2, the three expert reports of Wenzel, Kuehn and Mont, and a video that you don't know who created it, is all that you relied upon -- or you remember that you relied upon in formulating your opinions today.
A. No.
Q. What else is there?
A. I have -- I have been the recipient of countless electronic mail communications on -- on this subject, I have seen coverage of it in the trade -- trade press, I have had lec -- lectures and abstracts that I have -- that I have seen. I cannot recall the de -- details of any one of those. But in synthesizing what I think about this issue today, all of those, in addition to my own clinical experience, play a role in formulating the materials. So I think that inevitably, given the multiplicity and variety and the span of time over which this information has come to me, I think that there are going to be items that, almost perhaps even subconsciously, factor into my thinking on the sub -- on the subject.
Q. Well unfortunately I'm not a mind reader.

You understand that; right?
A. I -- I assume -- I assume that that's so.
Q. Okay. Do you understand we're here --
I'm here to take your deposition and to understand your opinions. You understand that; correct?
A. Yes.
Q. And I want to understand the methodology in formulating your opinions. You understand that; correct?
A. Yes.
Q. And understanding also what documents and information you used in formulating opinions that you relied upon. You understand that; correct?
A. Yes.
Q. And sitting here today it's my understanding, based on your testimony, that you do not have that information for me today.
MS. LEWIS: Objection, form.
A. Is that -- was --
Was there a question?
Q. You don't have all the documents or all the materials you are going to use or you relied upon in formulating your opinions; correct? You don't have a list.

A. Correct.
Q. All right. What I have is Exhibit 2; correct?
A. Yes.
Q. Okay. This electronic mail, is there anything in the electronic mail that you used or you relied upon in formulating your opinions?
A. The --
I am thinking primar -- primarily of the mass e-mails from stopsurgicalinfections.org and similar related organizations.
Q. Okay. With respect to any e-mails with counsel, any e-mails from counsel that -- that -- that provided information that you relied upon?
MS. LEWIS: Objection to the form of the question. It's asking for communication material, and you don't have to answer questions about any communications that you've had with counsel.
Q. Is there any in --
MR. ASSAAD: Actually, you're actually wrong. I'm allowed to --
If he's relying on any facts that you told him, I don't -- if it's in a communication, I have every right to know about it.
MS. LEWIS: If he -- if he knew about that

fact already, he is not getting that fact from counsel.
MR. ASSAAD: Okay. Stop coaching the witness, Ms. Lewis.
MS. LEWIS: That's -- I'm -- I'm --
MR. ASSAAD: You are coaching the witness.
MS. LEWIS: No, I am not coaching the witness.
MS. ASSAAD: If you want him to step out, we could have him step out, we could have a legal debate of whether or not it's confidential, but I don't want you to coach --
MS. LEWIS: He's not going to answer questions on communications.
MR. ASSAAD: I'm not asking about any communications.
Q. Is there any facts the defense gave you that you're relying upon in formulating your opinions?
A. Any facts?
Q. Yes.
A. Do you distinguish facts from materials?
Q. Any materials they gave you that you're relying upon, anything that they've given you that you're relying upon in formulating your opinions.
A. The expert opinions were provided to me by

counsel.
Q. Okay. So Jarvis and Stonnington.
A. The video that we discussed was provided to me by counsel.
Q. Anything else?
A. A test -- testing report on filters.
Q. Is that listed in Exhibit 2?
A. No, it is not.
Q. Why not?
A. Because I hadn't thought of it at the time I created Exhibit -- Exhibit 2.
Q. As of yesterday.
A. Correct.
Q. Okay. What else?
A. I can't say.
Q. When did you receive the depositions?
A. In the last several months.
Q. Did you receive the deposition of Al Van Duren?
A. I'm sorry?
Q. Al Van Duren. Do you know who he is?
A. Al Van -- Al Van Duren. Al Van Duren, that name sounds -- that sounds familiar. And again, whether the name sounds familiar because of seeing a paper of his, whether he was referenced in the expert

reports that I did -- did read -- read, I don't know, but the name sounds -- sounds familiar.
Q. Did you read his deposition? Simple "yes" or "no" or "I don't know."
A. I don't know.
Q. Okay. Did you read the deposition of Dr. Wenzel?
A. No.
Q. Did you read the deposition of Dr. Kuehn?
A. No. I believe I read their expert reports.
Q. Did you read the deposition of Dr. Mont?
A. I don't know.
Q. Okay. Can you tell me any dep -- any deposition that you've read from what subject matter it was dealing with, if it was a doctor, anything today?
A. I read -- I read parts of Dr. Kurz.
Q. Kurz?
A. Yes.
Q. Who is Dr. Kurz?
A. Dr. Andrea Kurz is a scientist and the author of an important paper in the area of surgical normothermia.
Q. Are you talking about the 1996 paper on thermoregulation --

A. Yes.
Q. -- and infection, surgical-site infection?
A. Yes.
Q. Do you consider her an expert in the field?
A. I consider her an expert in the field.
Q. Do you consider Dr. Sessler an expert in the field?
A. Yes.
Q. Have they done more research on normothermia than you have?
A. Yes.
Q. In fact, you have done no research on normothermia; have you?
A. Correct, except to the extent that I have to make decisions about how I manage the temperature of the patients I anesthetize.
Q. Let me ask my question again. And this is going to go a lot quicker if you answer my question. Okay?
I understand you're a treating physician. I understand what anesthesiologists do. We don't need to go there. My question is you, Dr. Hannenberg, have not done any research on normothermia; correct?
A. Well are you -- are you talking about laboratory re -- research, clinical studies, or are

you talking about re -- research in the sense of evaluating the available science in order to make a clinical decision?
Q. I'm --
Let's talk about clinical studies. Have you done any clinical studies?
A. No.
Q. Have you done any laboratory research?
A. No.
Q. Okay. You've read papers; correct?
A. Correct.
Q. Okay. And some of the papers we'll be talking about today; correct?
A. Yes.
Q. But you haven't done what Dr. Kurz or Dr. Sessler has done; correct?
A. Correct.
Q. Or any other people out in -- in -- who have published papers on normothermia; correct?
A. Correct. Other than an edit -- an editorial on the subject of surgical normothermia, I have not published on this subject.
Q. And you read the paper of Dr. Sessler; correct?
A. Correct.

Q. And how do you know Dr. Sessler?
A. Dr. Sessler and I served on a committee that developed a performance measure on perioperative normothermia.
Q. Okay. So we're going to get to that, but I just want to understand what is the universe of information you used to formulate your opinions, and my understanding right now is Exhibit 2, Dr. Wenzel, Dr. Kuehn and Dr. Mont's expert reports, a video of airflow, a testing report regarding filtration, and parts of Dr. Kurz's deposition; correct?
MS. LEWIS: Object to the form of the question.
A. Those materials did serve as the basis for my opinions, --
Q. Anything else?
A. -- but I think I've already out -- outlined the fact that I have seen trade press publications, --
Q. Which ones?
A. -- an e-mail --
I -- I cannot -- I cannot cite -- cite them. I haven't kept a record of those publications that I've seen over the course of a decade.
Q. But did you use them and look at them in creating Exhibit 3, your expert report?

A. With respect to what is in my expert report, my expert report has the citations of the materials that I point to in the text of the expert report. So the content of the expert rep -- report is one -- is one thing, the full range of my opinions on the sub -- on the subject is something else.
Q. Okay. But with respect to all the materials you used in formulating the opinions in your Exhibit -- in Exhibit 3, your -- your expert report, we've discussed those today; correct?
A. I'm -- I'm sorry. Say again.
Q. With respect to Exhibit 3, --
A. Yes.
Q. -- we have discussed all the materials that you have reviewed or looked at or considered in formulating your opinions that are in Exhibit 3, your expert report; correct?
A. Yes.
Q. Okay. I understand you have education, training and experience, but I'm talking about documents that you've looked at or considered. You understand that; correct?
A. Yes.
Q. Okay. Did you look at the Huang paper?
A. If you can show it to me I can --

Q. Well it's not listed here, so if it's not listed in Exhibit 2, have you -- did you look at it or consider it in formulating your opinion for your expert report?
A. No.
Q. What about the Zink paper?
A. I --
No, it did not factor into my expert report.
Q. What about the Moretti paper?
A. I probably have seen -- have seen it, but I would not say that it is part of the content of my expert report.
Q. What about the Sun paper. Do you know what the Sun paper is?
A. No.
Q. Okay. Sun with -- with Andrea Kurz, do you know what paper that is?
A. No.
Q. Okay. What about the Sessler/Olmstead/Kuplinger paper, do you know what paper that is?
A. No.
Q. Okay. What about Belani, does that name sound familiar?
A. Yes, it does.
Q. Did you review that paper?

A. I prob -- I probably did.
Q. Did you review that paper in formulating your opinions in Exhibit 3?
A. No.
Q. What about the Reed paper, "Evaluation of Intake Filtration: Internal Microbial Buildup in Airborne Contamination Emissions," did you review that paper in formulating your opinions in Exhibit 3?
A. No.
Q. You added Legg, Cannon, Hamer, "Do forced air patient-warming devices disrupt unidirectional downward airflow?" Did you look at any other Legg paper in formulating your opinions on Exhibit 3?
A. No.
Q. Okay. Did you find this Legg paper on your own or did -- was that provided to you by counsel?
A. That was, I believe, provided to me -- to me by stopsurgicalinfections.org.
Q. Okay. Did you review the Desari paper, "Effect of forced-air warming on the performance of operating theatre laminar flow ventilation?"
A. Yes, I think I did.
Q. In formulating your opinions in -- in Exhibit 3?
A. Well in -- in Ex -- in Exhibit 3 I address

Page 34

the proposition that forced-air warming devices disrupt laminar -- laminar flow. There are multiple sources of that proposition; I believe that is one -- is one of them. So that I was -- did not refer specifically to that paper but to the -- the opinion about forced-air warming and laminar flow --

Q. Does the Desari paper --

A. -- more generally.

Q. Does the Desari paper have to be included --

MS. LEWIS: Wait. Did you finish your answer?

THE WITNESS: Yes.

Q. Does the Desari paper have to be included in Exhibit 2 now? Would you include it?

A. I -- I -- I don't -- I don't see why not.

Q. Okay. So it should be another document -- a document that you considered in formulating your opinions of Exhibit 3?

A. Yes.

Q. Okay. So do you recall the paper written by Sessler, "Forced-air warming does not worsen air quality in laminar flow operating rooms?" Did you ever read that paper?

A. I recall -- I recall the title. Whether

Page 35

I've read it or not, I don't know.

Q. Okay. So you didn't -- you didn't consider that paper in formulating your opinions in Exhibit 3; correct?

A. Correct.

Q. Okay. Do you recall reading the paper by Belani, "Patient warming excess heat: The effects on orthopedic operating room ventilation performance?"

A. No.

Q. Do you know who Dr. Belani is?

A. No.

Q. He was -- he was the Chair of Anesthesiology at the University of Minnesota.

A. No.

Q. Did you read the Stocks paper on particles?

A. Did I read the Stocks paper? I don't recall.

Q. What about the Darouiche paper on particles and bacterial load?

A. No.

Q. I understand that on Exhibit 2 you looked at the letter to the editor -- well strike that.

Did you read the Albrecht paper, "Forced air warming: A source of airborne contamination in the operating room?"

Page 36

A. I believe I did.

Q. Okay. But you didn't put that in something that you considered in your ex -- for your expert report; correct?

A. Correct.

Q. Let -- let me ask you a question. Exhibit 2 is not in alphabetical order; correct?

A. Correct.

Q. So why would you stick four more items in the middle -- or not even in the middle, like randomly into Exhibit 2 and just -- instead of putting it at the end to make it easy for everyone to know what you added to your -- your Materials Considered?

A. That's where the curs -- cursor was -- was when I pulled the citation.

Q. Yeah. But then you -- you went from Melling to Scott and you jumped over Leitjens, so it's not like you continued writing four -- four directly in a row.

A. Well --

Q. I mean you put Legg, Wood, then you skipped -- then you -- then you put your cursor again and you went to Melling and you moved your cursor again and went to Scott. Why would you do that?

A. In order to look at what was already in

Page 37

the -- in the report, so scroll -- scrolling up and down through the document.

Q. So they're -- they're in order of what you reviewed? This is the order that it's in your -- in your report?

A. No. I had the original re -- report submitted previ -- previously. I was reviewing it on the computer screen, addressing omissions, and where the cursor -- cursor was -- it was not --

Had the original report been in alphabetical order, I probably would have inserted the new items in alphabetical order, but it was -- but it wasn't. I was reviewing the pri -- previously submitted report.

Q. So you -- are --

It's my understanding that -- that Materials Considered is -- kind of follows the same format as how it's cited in your report; correct?

A. It is cited in my report in relation to the commentary in the text of the report.

Q. I -- I understand. But my question is: If you look at page eight of your expert report, which is Exhibit 3, and you look at Exhibit 2, which is the documents called Materials Considered that you provided today, is the order that is on Exhibit 2 similar to what is in Exhibit 3, you just added where

those documents would go in relation to your report?
A. I'm not -- I'm not sure I understand what you're asking.
Q. For -- for example, you added Legg and Wood after McGovern. Okay? And McGovern is number 16 on Exhibit 3; correct?
A. Yes, it is.
Q. Is it my understanding that Legg and Wood are -- are around --
You're citing them for the same proposition or around -- same subject area as where McGovern is in your expert report?
A. No.
Q. Okay. So why does --
Why are you skipping around on Exhibit 2 in where you -- you added these new citations?
A. Exhibit 2 does not have any particular sequence after the content of the bibliography from the expert report appears.
Q. Well you put Legg and Wood between McGovern and Memarzadeh on Exhibit 2. You can look at Exhibit 2.
A. I -- I --
Q. Okay.
A. I -- I know.

Q. Why did you put those there?
A. As I -- as I said, the cursor on the screen was there when I had the references and -- and added them. The cursor on the screen was in a different place when I added the other references.
Q. Why did you move the cursor on the screen when you were editing the document?
A. Because I was look -- because I was looking at the pre-existing content of the doc -- of the document.
Q. Of Exhibit 2 or Exhibit 3?
A. Exhibit 2.
Q. So why did Melling go after patient warming?
A. Because I was on that point in the page when I paused to pull the reference for Melling and add it to the document.
Q. And why is Scott --
Why did you add Scott into your report, into your Materials Considered?
A. Because it influenced my opinion and it had previously been omitted.
Q. Okay. Where would --
Where did it influence your opinion in Exhibit 3?
A. It influenced my --

Q. Where in Exhibit 3, what part of your report of Exhibit 3?
A. Well I guess I would say that my opinion about the benefits and value of normothermia are in part informed by the content of -- of -- of Scott.
Q. Did you review the article Kimberger -- written by Kimberger, Held, Stadelmann, Mayer, Hunkeler, Sessler, Kurz titled "Resistive polymer versus forced-air warming: comparable heat transfer and core rewarming rates in volunteers?"
A. No.
Q. Okay. Do you take the similar position as Dr. Sessler in which you don't care how a patient is warmed as long as the patient is warmed?
A. I don't know that that's Dr. Sessler's opinion, but I think --
No. I -- I think I would dis -- disagree -- disagree with that, because, you know, part of the decision about how to -- how to warm the patient is two parts, it's efficacy and it's -- and it's safety. It's more than -- it's cost, it's cost, it's -- it's convenience, so there are multiple factors in determining the choice of warming technology.
Q. Okay. So you disagree with Dr. Sessler when he says that publicly at many 3M conferences.

MS. LEWIS: Object to the form.
A. I don't know that he says that -- that he says that publicly, but I've just told you what my opinion about patient warming is.
Q. Have you ever seen Dr. Sessler lecture on maintaining normothermia?
A. I -- I am sure I have. I can't recall when and where.
Q. So sitting here today, you don't remember.
A. Correct.
Q. Okay. Have you --
When was the last time you took a CLE on maintaining -- or CME on maintaining normothermia, if any?
A. I can't -- I can't recall taking a CME specifically on that subject.
Q. When is the last time you've attended any lecture -- CME, talk, anything -- on maintaining normothermia?
A. I don't -- I don't -- I don't recall.
Q. When was the last time you went to the ASA conference?
A. Last October.
Q. Okay. With respect to Exhibit 2, is this something that you drafted?

A. Yes.
Q. Okay. Did you ever review the deposition of Dr. Sessler?
A. I have reviewed a deposition of Dr. Sessler.
Q. Okay. Why wasn't that included in Exhibit 2?
A. Because I can't identi -- identify what content of that deposition informed my opinion.
Q. Exhibit 2 says "Materials Considered;" correct?
A. Yes.
Q. Correct?
A. Yes.
Q. It doesn't say "Materials Relied Upon;" correct?
A. Correct.
Q. Okay. So now we have Dr. Sessler's deposition. When did you review his deposition?
A. I don't recall.
Q. This year?
A. Most probably.
Q. Okay. Have you reviewed the deposition of Gary Maharaj?
A. No.
Q. Have you reviewed the deposition of --

ever --
Have you ever reviewed the deposition of Teri Sides?
A. No.
Q. Have you ever reviewed the deposition of Karl Zgoda?
A. No.
Q. Have you ever reviewed the deposition of Gary Hansen?
A. No, I don't think so.
Q. Have you ever reviewed the deposition of Troy Bergstrom?
A. No.
Q. Have you ever reviewed the deposition of Gary Maharaj?
A. I don't recall.
Q. Okay. Have you ever reviewed the deposition of Dave Westlin?
A. No.
Q. Have you ever reviewed the deposition of Dr. Elghabashi?
A. No.
Q. Do you know who Dr. Elghabashi is?
A. No.
Q. What about Mike Buck?

A. No.
Q. Do you know who Mike Buck is?
A. No.
Q. What about Dan Koenigshofer?
A. Other than the name sounding familiar, no.
Q. What about --
Did you review the deposition of Dr. Jarvis?
A. I don't believe I read his deposition. I --
Q. Have you read the deposition of Dr. Stonnington?
A. No. I read -- I read their expert reports.
Q. I understand that. I -- I know that's on Exhibit 2.
A. Yes.
Q. I'm asking about depositions.
A. Yes.
Q. Have you reviewed any medical records in this case?
A. In this case. In this case.
Q. Yes.
A. I reviewed medical records of Walton and Johnson.
Q. Okay. But you haven't reviewed any of the -- the upcoming trials and the medical records of those cases.

A. Correct.
Q. Okay. You do understand that Walton and Johnson are part of this case.
A. Yes.
Q. Okay. So when I refer to "this case," I'm talking about the Bair Hugger litigation in total. You understand that; correct?
A. Yes.
Q. Okay.
(Exhibit 4 was marked for identification.)
BY MR. ASSAAD:
Q. What's been marked as Exhibit 4 is a -- is a document -- the only document, the one and only -- produced by defendant in response to a subpoena to you. Do you recall --
Do you see this document?
A. Yes, I do.
Q. Okay. You --
Do you recall receiving a subpoena in this case?
A. Yes.
Q. Okay. Did you review the subpoena?
A. Yes. The subpoena -- subpoena relative to today's deposition?

Q. Yes.
A. Yes.
Q. Have you got another subpoena in this case not related to this deposition?
A. Not that -- not that I'm aware of.
Q. Okay.
A. I know that this document we're looking at, Exhibit 4, was requested. Whether that was requested under subpoena or not, I don't know.
Q. Did you --
Is this the only document that you provided to defendant in response to the subpoena, defense counsel?
A. What I produced --
So I've produced a curriculum vitae. What is rela -- related to the subpoena or not, I don't know. I produced what counsel asked me to produce.
Q. So you did not go through the subpoena and determine whether or not you had documents responsive to the subpoena, you just produced what defense counsel told you to produce?
A. We looked at -- we looked at the subpoena recently for the purpose of confirming that we had produced what was required by the subpoena.
Q. Did you create any notes?

A. No.
Q. You took no notes the entire time --
A. Correct.
Q. -- in this case at all.
A. Correct.
Q. Okay. Did you make any notes on any papers?
A. No, I did not.
Q. Okay. Any highlights?
A. No, I did not.
Q. Any communications with anyone besides counsel? E-mails?
A. No.
Q. Okay. Did someone tell you not to take notes?
A. Not -- not in this case, but in prior medical/legal work, yes.
Q. Okay. So the one case you did, the defense attorney told you not to take notes?
A. Correct.
Q. Did he tell you why?
A. That it was --
No.
Q. Okay. Did he give you instructions on how to be an expert witness?
A. I am not --

I don't understand that question.
Q. I mean did he give you --
Did he coach you on how to become an expert witness and how to answer questions, defense counsel?
A. Yes.
Q. Okay. What did he tell you?
A. To ans -- answer truthfully and completely and to be sure I understood the question.
Q. Okay. I mean as a doctor you take a lot of notes, don't you, in your practice?
A. Yes.
Q. Okay. Because that's how you can keep track of what you did and -- and what was done in the past; correct?
A. Correct.
Q. Okay. And not only do you take notes, but every other doctor takes notes and nurses take notes. It's just general practice to take notes; correct?
A. Correct.
Q. And there's actually a section that says "Progress Notes" in most medical records; correct?
A. Correct.
Q. But for acting as an expert, you don't take notes.
A. Correct.

Q. Okay. Is there something you're trying to hide?
A. No.
Q. Okay. Then why not take notes?
A. Because I was advised by counsel not to.
Q. Okay. I mean if you took notes about what you reviewed, then we would have a list of what you reviewed in this case; correct?
A. Presumably.
Q. You think we'd have a more accurate picture of what you reviewed?
A. We might.
Q. We might or most likely we would?
A. We -- we would have an additional resource to -- to consult.
Q. Well you don't even remember the depositions you've read; correct?
A. Correct.
Q. If you took notes as to what depositions you read, we'd have a record of what you read; correct?
A. Correct.
Q. And if you took notes of what documents you reviewed, we'd have all the documents that you reviewed; correct?
A. Correct.

Q. Okay. Note-taking is a good thing; isn't it?
A. I have been told that in this context it is not -- it is not.
Q. By defense attorneys?
A. Correct.
Q. Okay. I mean you teach your residents to take notes; correct?
A. I don't teach -- I don't teach residents now, but when I did -- when I did, yes.
Q. Yeah. I mean it would be almost malpractice if you didn't take notes; correct?
A. I'm not sure what medical practice and medical malpractice has to -- has to do with conduct as an expert wit -- expert witness, but it is certainly standard practice among physicians to make notes.
Q. I mean you -- you understand that there's almost 3,000 people that have filed cases in this litigation. Are you aware of that?
A. I'm aware of that.
Q. Okay. That's 3,000 people that had severe periprosthetic joint infections. Do you understand that?
MS. LEWIS: Object to the form.

A. If you say -- if you say so.
Q. I mean --
A. I know -- I know about the details of two of the cases.
Q. You know what a periprosthetic joint infection is.
A. Yes, I do.
Q. It's a serious infection; correct?
A. Yes.
Q. Okay. Some people have --
Some people die. You understand that; right?
A. Yes.
Q. Some people have amputations. You understand that.
A. Yes.
Q. And most if not all, probably 90 -- at least 90 percent have additional surgery. You're aware of that; right?
A. I'm not aware of that statistic.
Q. So you understand that this is a serious case.
A. I understand this is a serious case.
Q. And I have the right to understand all your opinions and the basis for your opinions. You

understand that; correct?
A. Yes.
Q. And that's even required under the -- the Federal Rules of Civil Procedure, Rule 26, that you need to identify the facts and basis for all your opinions. Do you understand that?
MS. LEWIS: Objection to form.
A. I know nothing about Federal Rule 26.
Q. Were you -- were you told that I -- that I'm allowed to understand all the facts and basis of -- of -- of your opinions?
MS. LEWIS: I object to your discussing any communications that you've had with defense counsel.
Q. Was it your understanding when you wrote the report, Exhibit 3, that you must convey all your opinions and the facts and basis behind those opinions?
A. I think I've stated in Exhibit -- Exhibit 3 that it is not a fin -- final or necessarily a comprehensive re -- report.
Q. Where did you get the idea that you didn't have to have a final report by June 2nd, 2017?
A. If I can quote --
Q. I -- I know your report. I'm asking where did you get the idea or who told you that your report

didn't have to be filed by June 2nd, 2017?
A. The report was -- was -- was filed. It doesn't -- it doesn't mean that I necess -- necessarily included every thought or i -- idea about -- about the case. It doesn't mean that it is an exhaustive recitation of all my opinions.
Q. So your report's incomplete?
A. I wouldn't characterize it as -- as incomplete. It is not an exhaustive recitation of all my opinions.
Q. You know what a deadline is; correct?
A. Yes.
Q. Okay. The deadline was June 2nd, 2017. You understood that; correct?
A. Yes.
Q. Okay. So why isn't your -- why isn't all your opinions in your report?
A. Well I may have thought about -- something about this report on June 3rd.
Q. Well has something come up in the science or research of normothermia between June 3rd -- maintaining normothermia between June 3rd and today that you're aware of?
A. Has something --
Are you referring to a published --

Q. Publication.
A. -- study?
Not in that -- not in that interval. But that's a different matter from my opinion taking -- taking shape or another perspective on a question I find --
Q. Your opinion could change; is that what you're saying?
A. -- my opinion -- my --
MS. LEWIS: Gabe, would you let him finish --
Q. Your opinion could change?
MS. LEWIS: -- before you start your next question?
Q. Your opinion can change?
A. My opinion can change.
Q. Okay. So if that's the case, I might be able to convince you that maintaining normothermia is junk science today; correct?
A. I doubt it.
Q. Pretty good.
MR. ASSAAD: Let's take a break.
THE REPORTER: Off the record, please.
(Recess taken.)
BY MR. ASSAAD:

Q. Going back to Exhibit No. 2, I don't see any internal 3M documents that you reviewed. Have you ever reviewed any internal 3M documents in formulating your opinions?
A. I don't recall that I have.
Q. Well if it's not listed in Exhibit 2, that means you never reviewed any internal 3M document, correct, in formulating your opinions?
A. In formulating my opinions, that's -- that's correct.
Q. So you have reviewed internal 3M documents?
A. I -- I don't -- I -- I just said I didn't recall whether I had or not, but if I -- if I did, they were not material to creating my opinions.
Q. But you considered them.
A. I'm not sure what -- I --
So some things I may consider and dismiss as not important in creating an opin -- an opinion on a matter, so it's -- so I'm not -- I'm not sure whether that counts as considered in -- in your view or in the context of your question.
Q. Well you -- you saw --
You mentioned there was a filtration study that you looked at; correct?
A. Correct.

Q. Okay. And it was an internal 3M document?
A. I don't -- I don't know whether it was or -- was or not.
Q. You don't know?
A. I don't know.
Q. Do you have it here with you today?
A. No, I don't.
Q. Did you bring anything with you today?
A. No.
Q. Do you think if you brought your documents you would be able -- you brought your documents you would be able to answer these questions?
A. If I looked at that particular document, it might tell me whether it was an internal 3M document or not, but I don't know that for sure.
Q. Have you ever done a case study as a doctor?
A. I'm not sure what you mean by "a case study."
Q. Like where you talk about a patient in front of a bunch of students.
A. Yes.
Q. Okay. Do you go into the case study and discuss with your students about the case without any of the medical records?
A. Seldom.

Q. Okay. Because it's good to have a reference material when you discuss a subject; correct?
A. In some circumstances, yes.
Q. I mean when you're having a case study and talk about a patient, sometimes you even make copies of the medical records for others to review and -- and look over so you can have an educated conversation with them; correct?
A. Sometimes we do that.
Q. Okay. Or you have a PowerPoint presentation; correct?
A. Correct, I have had PowerPoint presentations.
Q. And in fact, when you give presentations you probably use a PowerPoint presentation to document certain things that you rely upon or you looked at when you give a presentation; correct?
A. Well I'll go so far as agreeing I use PowerPoint --
Q. Okay.
A. -- present -- presentations.
Q. Okay. And you might look at the studies that you're referring to or some medical records that you're -- you're discussing; correct?
A. I don't --

I might look at them? What do you mean?
Q. Well I mean if you're talk -- giving a presentation on thermoregulation, you might have some of the studies that you are relying upon that you're -- that you're discussing with the people you're giving the presentation to; correct?
A. In the PowerPoint, --
Q. Yes.
A. -- is that what you mean?
Yes.
Q. Okay. Why did you remove Dr. Wenzel's science day presentation, May 19th, 2016, from Exhibit 2?
A. Well I don't know that I did -- that I did.
Q. If you look at Exhibit 1, it's third from the bottom; in Exhibit 2 it's no longer there.
A. Well, inadvertent.
Q. You inadvertently deleted something?
A. Yes.
Q. Did someone tell you to delete it?
A. No. I said it was inadvertent.
Q. How do you inadvertently delete something from a -- from a document?
A. I was editing the document, as you know.
Q. Okay. So you're not relying any more --

I mean did you consider the science day presentation?
A. Yes, I did.
Q. Was it --
What presentation was it? Was it a transcript?
A. It was a PowerPoint.
Q. A PowerPoint. Okay.
Were you at science day?
A. No.
Q. Are there any other drafts of the Materials Considered?
A. No.
Q. And would it be fair to say you deleted this yesterday, the Dr. Wenzel science day presentation?
A. Yes.
Q. Were you with counsel when you were editing the Materials Considered?
A. No, I was not.
Q. Did you already meet with counsel, prior to editing the materials, counsel yesterday?
A. Yes.
Q. Okay. So you met with counsel yesterday; correct?
A. Yes.

Q. And then you went back and edited the Materials Considered; correct?
A. Yes.
Q. Okay. With respect to Exhibit 3, that's a -- that's a complete copy of your opinions in this case; correct?
A. Yes.
Q. Have you reviewed it --
Did you review it in preparation of today's deposition?
A. Yes.
Q. How many times did you read it?
A. I have read it countless times -- countless times since first drafting it.
Q. So between June 2nd and today you've read it -- you've read it countless -- countless times?
A. Between June 2nd and today, five times --
Q. Five times.
A. -- is my best estimate.
Q. And you believe it's correct?
A. Yes.
Q. And you stand by all your opinions?
A. Yes.
Q. Do you want to make any changes to your expert report?

A. No.
Q. Were you aware that science day was off the record?
A. No.
Q. Okay. Were there --
With respect to Exhibit 4, this is an invoice from you to Deborah Lewis; correct?
A. Correct.
Q. By the way, have you spoken with anyone internally at 3M regarding your opinions?
A. No.
Q. Okay. Do you recall --
Has anyone from 3M made any edits to your expert report?
A. No.
Q. Okay. Is this the entire -- from --
Is this your entire work on this case from June 6 -- I'm sorry -- April 6th to June 1st, 2017?
A. To which date?
Q. June 1st, 2017.
A. Yes.
Q. And this is all your work actually up to June 14th, 2017; correct?
A. Correct.
Q. Okay. How many hours have you billed since

June 14th, 2017?
A. I don't -- I don't recall.
Q. Do you keep track of your hours?
A. Yes.
Q. Okay. Where do you keep track?
A. On my computer.
Q. On your computer. Okay.
Can you give me a rough estimate?
A. Probably --
A rough estimate, probably an additional 15 hours.
Q. Fifteen. And that would be reviewing your report and preparing for the deposition?
A. Yes.
Q. Did you review any additional articles?
A. Did I review any additional articles when?
Q. Between June 14th, 2017 and today that's not in Exhibit 2 or we've discussed today.
A. No. I think we've discussed everything.
Q. Okay. And would it be fair to say that with respect to your expert report, that Exhibit 4 is a sum of all the time in preparing and formulating your opinions outlined in Exhibit 3?
A. Judge -- judging by the dates of the invoice and the report, I think that's a fair conclusion.

Q. So the answer to my question is yes.
A. Yes.
Q. Okay. And I assume that all the time that you worked on your expert report, you -- you described it as "Draft expert letter;" correct?
A. I'm not sure I can draw a distinction between rev -- reviewing documents and -- and drafting the letter.
Q. You can?
A. No, I can't.
Q. You understand that "review" is different than "draft."
A. Well I may do them contemporaneously.
Q. Okay. My question is: When you had pen to paper, would that be described as "Draft expert letter?"
A. If that were the principal activity, yes.
Q. Okay. You might be looking at documents in drafting your report, but "Draft expert letter" is pen to paper.
A. I think that's a fair way to characterize it.
Q. Okay. So we're looking at 95 minutes, 130 minutes, 110 minutes, and 105 minutes; correct?
A. It looks that way, yes.

Q. Okay. That's a total of 440 minutes you spent on pen to paper on your expert report; correct?
A. Apparently.
Q. Which is approximately 7.33 hours. Does that sound about right?
A. Yes.
Q. And you charge $500 an hour?
A. Yes.
Q. Okay. Have you ever been retained as an expert in this case -- in any case but not have a deposition done?
A. Yes.
Q. Approximately how many times?
A. Three or four.
Q. Were they for the defense or the plaintiff?
A. They were for the defense.
Q. So you've never been retained by a plaintiff?
A. Correct.
Q. Have you ever been asked to be -- to rep -- by a plaintiff's attorney to act as an expert?
A. No.
Q. Did you make any changes to your expert report after May 25th, 2017?
A. I don't recall.

(Exhibit 5 was marked for identification.)
BY MR. ASSAAD:
Q. What's been marked as Exhibit 5 is a copy of your curriculum vitae provided to us on June 2nd, 2017. Is this the most-up-to-date copy of your curriculum vitae?
A. Yes, it is.
Q. You have made no changes since June 2nd, 2017?
A. Correct.
Q. Okay. No new publications?
A. No, I don't think so.
Q. Okay. Are you board certified?
A. Yes.
Q. When did you become board certified?
A. 1984.
Q. Did you have to --
Was there a recertification or were you grandfathered in?
A. I was grandfathered in --
Q. Okay.
A. -- but I have recertified anyway.
Q. Okay. Are you still practicing medicine?
A. Not since January 1st.

Q. Okay. And now you're a consultant or on advisory for a couple companies; correct?
A. No.
Q. You don't --
You're fully retired?
A. No, I'm not a consultant for companies.
Q. Well it says "Principal Consultant, ORDxRx..."
A. That is -- that is a -- that is a company of which I'm a princ -- a principal.
Q. Were you at one --
Okay. So you're a principal consultant.
A. Yes.
Q. Are you a shareholder?
A. Yes.
Q. What percentage?
A. In the teens probably.
Q. Okay. Do you know Ms. Hughes?
A. Ms. Hughes?
Q. Antonia Hughes, an expert in this case.
A. No.
Q. Okay. It also says "Chief Quality Officer (interim), American Association of Anesthesiologists." Is that still current?
A. Yes.

Q. Okay. And it says "Senior Research Scientist, Brigham & Women's Hospital" --
Is that "Ariadne Labs?"
A. Ariadne Labs.
Q. Is that still current?
A. Yes.
Q. Are those the only positions that you're holding right now?
A. Well I -- I'm a member of boards of directors of foundations, but as far as employment is concerned, those are the only ones.
Q. Any foundations dealing with anesthesiology?
A. Yes.
Q. What foundation?
A. The Anesth -- the ASA Charitable Foundation and the Lifebox Foundation.
Q. What is Lifebox?
A. Lifebox is a global health foundation -- foundation working in surgical safety.
Q. When you talk about surgical safety, are you talking about safety for the patient?
A. Princ -- principally, although not -- not exclusively.
Q. You would agree with me that safety is paramount with respect to patients.

A. Safety is paramount with respect to patients.
Q. And physicians should do everything -- strike that.
Do you have any experience designing a medical device?
A. Many -- many years ago I began the process -- and quickly abandoned it -- of developing a tooth guard, a tooth guard for intubation, but it was -- the design was never completed. It was never brought to market or patented. So that is the limit of my experience.
Q. Do you have any patents?
A. No.
Q. Have you ever dealt with the FDA?
A. Have I ever dealt with the --
Q. With a medical device issue or --
A. No.
Q. Okay. You mention in your expert report that you've acted as an anesthesiologist on approximately 400 total joint arthroplasties. Does that sound about right?
A. Yes, it does.
Q. And that's over your career of -- since 1983?

A. 1980, yeah. Well it depends whether you count residency or not -- or -- or not. But it's a rough estimate from 1984, roughly, which is when I finished training.
Q. So what are you counting the 400 as, from when you graduated medical school or when you finished your residency?
A. After I finished my res -- residency. But it's a rough -- it's a rough estimate.
Q. So it's about three or four a year; correct?
A. Three or four a year?
Q. I'm sorry.
A. It's about -- about --
Well I guess that -- that comes out to about 15, 15 a year.
Q. I'm sorry, 15 a year.
A. That when framed -- when stated that way, that sounds like an underest -- an underestimate, particularly in the later years of my practice when the volume of that kind of surgery had increased substantially.
Q. Do you have --
A. So I would -- so it's a --
It probably is -- is more but by order -- order of magnitude is a reasonable estimate.

Q. When you say "more," are you talking about like double?
A. No. But I mean 25, 30 percent more -- more. As -- as I said, it's not something I keep regular count of, but when I think back on, you know, how many -- how many per week over how many weeks and so -- so forth, the estimate is in that range.
Q. Do you have --
Do you work with nurse anesthetists?
A. Sometimes I do, yes.
Q. Okay. Do you supervise nurse anesthetists?
A. Yes.
Q. You don't believe that they should be able to practice anesthesiology without supervision; correct?
A. Correct.
Q. You've actually written an article on that or you -- you commented in an article regarding an issue about allowing nurses to take on full responsibility for anesthesiology; correct?
A. I don't know what you're reference -- referencing, but I believe that that is -- that is my opinion.
Q. Okay. I mean at one time the Institute of Medicine wanted to give nurses a bigger role and you

argued against it. Do you recall that?
A. I don't -- I --
I have publicly stated that op -- that opinion. Whether it was in reference to something that the Institute of Medicine said or someone else said, I'm not sure. But I have publicly stated that opinion.
Q. And you said that patients want doctors, not nurses; correct?
A. I have stated that public opinion polls suggest that that's the case.
Q. And you argued about pushing doctors' jobs into nurses' hands; correct?
A. That doesn't sound familiar to me.
Q. Do you recall an editorial in the New York Times that you were commenting on about giving --
The New York Times had an editorial about giving nurses bigger roles. Do you recall that?
A. I do recall that.
Q. Okay. And you said it would be dangerous to allow nurses to administer anesthesia care.
A. Without supervision.
Q. Yes.
A. Well --
Q. Yes.

A. -- do you want to rephrase that?
Q. Well you -- you agree that allowing nurses to -- to administer anes -- anesthesia care without supervision would be dangerous; correct?
A. Correct.
Q. Well how many operating rooms can you run at one time with -- with nurse anesthetists by supervising them?
A. What is the meaning of "can?"
Q. Like how many --
How many operating rooms have you ran at one particular time simultaneously?
A. Two.
Q. One with a nurse anesthetist and you?
A. No, two nurse anesthetists and me.
Q. Okay. Now with respect to your CV, so Ariadne --
How do you pronounce that?
A. Ariadne.
Q. -- Ariadne Labs, they put out a checklist for surg -- surgical patient safety.
A. Correct.
Q. Okay. And one of them is using a forced-air warming de -- or warming device, correct, on the checklist?

A. I'm not familiar with that.
Q. Okay. By the way, when you do -- when --
How long does a total knee or total hip arthroplasty take when you were an anesthesiologist?
A. Approximately an hour, sometimes -- sometimes as much as two.
Q. Okay. I'm talking about like a primary arthroplasty.
A. It var -- it varies by surgeons, size of patients, many factors, the type of hardware being -- being used, so I can't state a precise number of -- applicable to all such operations. So there's a range.
Q. Would it be fair on average it would be about an hour?
A. An hour and a half.
Q. You think an hour and a half?
A. Yes.
Q. Did you read Dr. Mont's deposition where he said that he does it in 25 minutes?
A. I -- I don't recall -- recall that he said that, but if he did, he did.
Q. Do you think that's achievable to do, from -- from incision to close, in 25 minutes?
A. Well it depends what he's -- what he's

counting towards the -- towards the 25 minutes.
Q. From incision to close.
A. I -- I've never -- I've never seen a total joint replacement done in twenty -- skin to skin in 25 minutes.
Q. Okay.
A. Whether it's possible or not, I can't comment.
Q. You agree with me that patient warming is not indicated for surgery that lasts one hour or less; correct?
A. No.
Q. You disagree?
A. I disagree.
Q. Okay. Do you believe perioperative warming actually works in the first hour?
A. I think the longer perioperative warming is applied, the more likely you are to achieve normo -- normothermia, so it's a -- so it's a continuum.
Q. That wasn't my question. Do you believe that main -- like patient warming in the first hour has any effect on a patient's temperature?
A. Yes, it does.
Q. In the -- in the first hour.
A. Yes, it does.

Q. Now in looking at Exhibit 5, can you direct me to any article in which you have discussed thermoregulation?
A. I think the only -- the only one is Anesthesia & Analgesia in 2008.
Q. 2008. Was it a peer-reviewed article?
A. It's an invited editorial.
Q. Is it under "PUBLICATIONS?"
A. Yes. Page 15, about halfway down.
Q. Okay. And that was an editorial that you wrote with Sessler -- Dr. Sessler.
A. Yes.
Q. And it wasn't peer-reviewed; correct?
A. Correct.
Q. Okay. Because it was an editorial.
A. Correct.
Q. Okay. And that really had nothing to do with the science of maintaining normothermia, it was more with the -- with the -- whatchumacallit -- the -- I'll get the right word in a second -- pay for performance; correct?
A. Correct.
Q. Would you agree with me that most of your talks and literature deal with pay for performance or the economics of anesthesiology?

A. I -- I haven't done the math, but I have spoken frequently on those subjects.
Q. I mean let's go through your -- your talks starting on page six.
Oh, before I get there, what is this medical malpractice committee that you're on?
A. Committee?
Q. Yes. Hold on. The Massachusetts --
A. Medical malpractice tribunal?
Q. Yes.
A. The law in Massachusetts requires that medical malpractice cases be heard by a three-member tri -- tribunal before they're allowed to go -- allowed to go forward. The three-member tribunal is constituted by a physician, a judge, and an attorney. I think there is a requirement that it be a physician of the same specialty. So from time to time over many years -- although not recently -- I've been asked to serve on those -- those tribunals as the anesthesiologist member.
Q. When -- when -- when a -- someone wants to sue an anesthesiologist?
A. Yes.
Q. How many times did you sit on the panel?
A. Probably eight or 10, roughly.

Q. In any of those instances, did you ever find that the anesthesiologist was negligent?
A. The purpose of the tribunal was not to make a judgment about whether the anesthesiologist was negligent.
Q. What was the purpose of the panel?
A. Whether it met a stan -- the -- the standard for allowing it to go to trial.
Q. What standard is that?
A. Is that the -- the evi -- the evidence presented supported an expert opinion that there was -- well "supported the expert opinion" -- that the ex -- the expert opinion relied on documented fact in -- in the alleg -- in forming the allegation.
Q. Did you ever vote to allow a case to go forward?
A. Yes.
Q. Did you ever vote for a case not to go forward?
A. Yes.
Q. Approximately how many times for a case to go forward?
A. I --
The major -- the majority of the time.
Q. Okay. You use the term "relative value"

numerous times in your CV. What is relative value with respect to anesthesiology?
A. Relative value refers to a -- a -- a payment system of aligning different physician services according to their relative value. The relative val -- value itself reflects three components: the physician work involved, the practice expenses involved, and the cost of professional liability insurance for those providing that service.
Q. And would it be fair to say that a lot of your work done in the past dealt with trying to educate and work to increase the payments made to anesthesiologists?
A. Yes.
Q. Okay. So in other words, a lot of your lectures dealt with the money.
A. They dealt with the relative value payment system.
Q. The money.
A. Okay.
Q. All right. Again today it's about the money; right?
A. If you say.
Q. I'm asking what you say. I mean we could go one by one and I could go and ask you, but a lot of it

has to do with the money.
A. Sure.
Q. Okay.
A. Yeah.
Q. Like, for example, number one on page six, invited lecture, presentation, "Anesthes -- Anesthesia Reimbursement...;" correct?
A. Yes.
Q. That's about the money; correct?
A. It's about the mon -- money and the methodology underlying the money.
Q. Okay. Next one, "Basics of Anesthesia Economics," that's about the money as well; correct?
A. Yes.
Q. Next one, "Basics of an Anesthesia Agreement," that's about creating agreements with hospitals to make more money; correct?
A. It's not about agreements with hospital -- with hospitals, it's about agreements with payers.
Q. With payers.
I mean it's about how to get paid the most for your services; correct?
A. It's about how to get -- get paid an equitable amount for our services.
Q. "The Changing Business of Anesthesia,"

that's about the economics of anesthesia; correct?
A. Yes.
Q. "The Economics of Private Practice" again is about the economics of anesthesia and how to increase your profits; correct?
A. The -- that is --
That one is not so much about increasing your profits, it's more methodological, it -- it being a presentation for residents.
Q. I mean the next two down, "Ins and Outs of Anesthesia Reimbursements," that's about the money; correct?
A. It is about the method of payments from payers to anesthesiology practices, from anesthesiology practices to the employees of those practices, so it is financially oriented.
Q. It's about the money; correct?
A. Yes.
Q. Okay. Two more down, "The Perils of RBRVS Payment in Anesthesia." What's RBRVS?
A. Resource Based Relative Value System.
Q. So it's about the money; correct?
A. Yes.
Q. "The Perils of Medicare RBRVS," that's about the money; correct?

A. Yes.
Q. And then "Anesthesia and Medicare," that's also about reimbursement from Medicare; correct?
A. Yes.
Q. It's about the money; correct?
Yes?
A. Yes.
Q. Okay. "Basics of Anesthesia Reimbursement," that's also about the money; correct?
A. Yes.
Q. "Emerging Trends in Reimbursement...," that's about the money, correct?
A. Yes.
Q. Let's go a couple down, "Analyzing the Profitability of Anesthesia Fee Schedules," that's about the money; correct?
A. Yes.
Q. "New Trends in Anesthesia Reimbursement," that's about the money; correct?
A. Yes.
Q. Okay. So you agree that most of these are about the money; correct?
A. Yes.
Q. Okay. Very little science, scientific research, all about the money; correct?

A. Yes.
MS. LEWIS: Objection to form.
Q. In fact, there's very little scientific research in these invited presentations; correct?
A. In that -- in that period of time, yes.
Q. We go to page seven, number two, "Commercial Payments Based on the Medicare Fee Schedule," that's about the money; correct?
A. Yes.
Q. Next one, "Introduction to Anesthesia Economics," that's about the money; correct?
A. Yes.
Q. I mean I --
Almost every single one of these is something to do about the money; correct?
A. In that period of time, yes.
Q. Okay. So would you agree with me that most if not all invited lectures on page seven is about the money?
A. On page seven?
Q. Yes.
A. Sure.
Q. Okay. Let's go to page eight. Number two, "Medicare Forecast 2004," that's about the money; correct?

A. Yes.
Q. "Anesthesia Reimbursement...," that's about the money; correct?
A. Yes.
Q. "Payment for MAC and Conscious Sedation," that's about the money; correct?
A. Yes.
Q. "Coding and Compliance Considerations in Monitored Anesthesia Care," that's about the money; correct?
A. Yes.
Q. "Professional Fees and Other Departmental Financial Support," that's about the money; correct?
A. Yes.
Q. "Anesthesia Economics...," that's about the money; correct?
A. Yes.
Q. Okay. You agree with me that most if not all on page eight are invited lec -- presentations about the money?
A. Yes.
Q. Okay. Let's go to page nine. First one, "Perioperative Temperature Management," 2005, is that about the money?
A. No.

Q. Was it not --
Wasn't part of that pay for performance?
A. A part of that lecture? No.
Q. Are you sure about that?
A. Yes.
Q. Okay. Is that the one where you saw Dr. Scott Augustine?
A. No.
Q. Okay. But the next one is "Pay For Performance...;" correct?
A. Correct.
Q. That's about the money.
A. Yes.
Q. "The Hospital Stipend Goldrush," that is about the money?
A. Yes.
Q. "Pay For Performance...," next one, is that about the money?
A. In part.
Q. Okay. And the next two or three are about pay for performance; correct?
A. In part.
Q. Okay. You have "Malignant Hypo -- Hyperthermia;" correct?
A. Yes.

Q. That's not any --
That doesn't deal with any issues in this case; correct?
A. Correct.
Q. All right. Would you agree with me that except for one or two on page nine, that most of these invited presentations are about the money?
A. Yes.
Q. Okay. And also the politics to -- to -- to deal with reimbursement; correct?
A. What are you referencing?
Q. "Science, Politics, Press and Money."
A. That is about the activities of the American Society.
Q. Of --
A. Anesthesiologists.
Q. -- anesthesiologists; correct?
A. Yes.
Q. Which at one time you were the president; correct?
A. Correct.
Q. And it's a -- and it has -- it's a lobb --
They have a lobbying group; correct?
A. Yes.
Q. Okay. And you donate to the lobbying group

Page 86

for the ASA; correct?
A. Correct.
Q. Okay. So page 10, first one, "Pay For Performance and the Anesthesiologist," that's about the money; correct?
A. It's about the mon -- money, but like all the discussions of pay for performance, it is about managing clinical care to meet the pay-for-performance standards, so it's both about the mon -- money and clinical be -- and clinical behavior.
Q. Now pay for performance is where you get additional money for certain measures; correct?
A. For certain measures.
Q. They don't deduct money from you; correct?
A. Well it depends when, when you're -- when you're talking about, because in the current program, yes, they -- yes, they do deduct money -- deduct money.
Q. Okay. But during this time, pay for performance in 2017, it would add additional money; correct?
A. Correct.
Q. Okay.
A. Correct, for those physicians who achieved the benchmarks established in the pay-for-performance

Page 87

program.
Q. When did they start -- when did they start deducting money for not meeting the pay-for-performance standards?
A. Well they --
Based on this year's performance, they will deduct mon -- money in the 2019 payments, so there's a two-year-cycle lag.
Q. Oh. And how long has that been going on?
A. This year.
Q. This is the first time this year they're doing that?
A. Correct.
Q. Okay. So up until 2017, pay for performance was additional money to meet certain outcomes.
A. Certain outcomes or re -- or reporting standards.
Q. Reporting standards. Okay.
So let's go to page 10. You have "The Hospital Stipend Goldrush." That's about the money; correct?
A. Correct.
Q. "The Future of Anesthesia Practice...," that's about the money; correct?
A. I don't recall the content of that.

Page 88

Q. "Pay For Performance...," that's about the money; correct?
A. As I have said before, it's about the -- the money and the clinical practice required.
Q. It has a money component.
A. It has a money component.
Q. Okay. Let's go down. "Medicare Reform, Quality and Pay For Performance," that has to do with money; correct?
A. That has something to do with the money.
Q. Would you agree with me that most on page 10 is dealing with the money issues and practice issues of anesthesiology?
A. Yes.
Q. Okay. Nothing scientific on -- on page 10; correct?
A. That's right.
Q. Okay. No research on page 10; correct?
A. In the sense that I was not presenting my original research -- research, that is -- that is true.
Q. And when I say "research," I'm talking about scientific research dealing with patient care.
A. Well the curr --
The pay-for-performance standards are

Page 89

grounded in scientific -- in scientific research, so in that -- in that sense it is not devoid of -- of science.
Q. I guess my question is: No research with respect to like clinical studies or research on patient care, it was more of how certain standards and pay for performance were going to be met.
A. In explain -- in explaining what the pay-for-performance standards are -- are, particularly with respect to process measures; that is, a standard for a particular activity of care, explaining the science that links that activity and care -- care to a patient outcome is based on scientific studies. So frequently, in describing the pay-for-performance stan -- standards, it would be important to explain why do we have this measure about perioperative temperature, for example, and what is the link -- linkage between warming a patient and an important outcome, why do we have -- why do we have a measure on this, and to some extent the editorial that we talked about a moment ago was meant to answer -- answer that question. But in all of the pay-for-performance talks that you have been referencing, that was, in most instances, a component of the presentation.
Q. But you're referencing articles, you're not

discuss --
You're referencing research articles, you're not presenting research articles; correct?
A. I don't understand the difference between --
Q. For example --
A. -- referencing and presenting --
Q. Okay.
A. -- a research article.
Q. Well -- well, for example, I'm Andrea Kurz and I just came out with my 1996 study, "I'm going to talk about it, and here's my study and this is the basis of my study." That's presenting a research paper; correct?
A. That's presenting my own research paper.
Q. Yes.
A. Is that the distinction you're trying to make?
Q. Yes, or -- yes, or compared to --
A. Okay. Correct.
Q. -- "Hey, we have this - these outcome measures for thermoregulation. And by the way, look at Andrea Kurz's article of 1996." That's what you do; correct?
A. Yes.
Q. Okay. Let's go down -- more down page 15 --

or I'm sorry, page 10. You have, you know, six from the bottom, "Payment Issues Update." That's about the money; correct?
A. Yes.
Q. "Pay For Performance," that's about the money; correct?
A. Well I'll say -- I'll -- I'll -- I'll say it again: The discussions about pay for performance have a financial aspect to -- to them, but the explanation of the basis of the performance mea -- measures has a scientific component to it.
Q. I understand that, doctor. But people are not --
You're not giving a lecture on the benefits of normothermia and its scientific basis behind it, you're saying maintaining normothermia and it's going to affect pay for performance; correct?
A. It's -- it's both. I mean the reason we have these performance measures and created them was to drive improvements in care, and that is, as much as anything, the message of the presentations on pay for per -- pay for performance.
Q. By the way, SCIP-10 is no longer in existence; correct?
A. SCIP-10 -- SCIP-10 is no longer in

existence, but the physician quality measures that is analogous is still in existence.
Q. But SCIP-10 is no longer in existence; correct?
A. Correct.
Q. And that was dealing with thermoregulation; correct?
A. Correct.
Q. Go to page 11.
Well, you agree with me that most of page 10 deals with some issue about pay for performance or money of anesthesiologists.
A. That's correct.
Q. Okay. "A Visit to the Sausage Factory," what's that about?
A. That was a pre -- presentation made in Great -- in Great Britain about American healthcare reform and The Affordable Care Act.
Q. By the way, you agree with me that 3M -- or Arizant at the time -- was involved with the, quote, unquote, lobbying to get the SCIP measures passed; correct?
A. I don't know that.
Q. Were you involved with the SCIP measures?
A. Not -- not directly. I was involved with

the physician measures and --
I was involved with the SCIP measures only insofar as we were asked to harmonize the physician normothermia measure with the SCIP-10.
Q. Where is the physician normothermia? Where can I find that?
A. You can find it on the second and third items in Materials Considered.
Q. Oh, the Centers for Medicare & Medicaid?
A. Yes.
Q. Okay. Now you agree with me that there's nothing on page 11 that deals with maintaining normothermia, the actual research.
A. There's talk on performance measur -- measurement in anesthesiology, which, as I have previously said, would include -- include the scientific basis of the performance measures.
Q. I understand that. But you -- you're referring to other people's research in the pay for performance; correct?
A. Yes.
Q. There's nothing on page 11 that deals with any type of research that you've done on maintaining normothermia.
A. I think we've previously esta -- established

that I have not personally conducted basic clinical science research on temperature management.
Q. I just like to be a little bit thorough just in case something might trigger your brain later on to saying, "Oh, actually I did something."
So let's look at page 12. There's nothing on page 12 that deals with any type of research that you did regarding maintaining normothermia; correct?
A. Correct.
Q. Okay. And the same thing for page 13, there's nothing in there that deals with maintaining normothermia, any research that you did; correct?
A. Correct.
Q. Okay. When you were a visiting professor or named lecturer, did you do any research under that section with respect to maintaining normothermia?
A. No.
Q. Now you agree that many of your publications deal with the actual practice of anesthesia with respect to fee schedules or profitability or relative value.
A. I did not hear the question.
Q. With respect to publications, would you agree with me that most if not all of those publications deal with -- let's just say most deal

with the anesthesia practice itself, you know, Medicare fee schedule, profitability, payments?
A. Most.
Q. Okay. And sitting here today, based on pages -- on 11, there's nothing -- or on page -- I'm sorry, page 14, there's nothing on page 14 that describes any type of research that you've done on maintaining normothermia; correct?
A. Correct.
Q. And the same thing with page 15, there's nothing on page 15 that you've done that deals with maintaining normothermia; correct?
Research.
A. There's nothing that presents original clinical or basic science research by myself.
Q. Okay. And on page 16 as well, there's nothing on page 16 that deals with anything that describes any research that you've done on maintaining normothermia; correct?
A. Correct.
Q. So basically with all your --
Would it be fair to say that with respect to your knowledge of maintaining normothermia, you would defer to people such as Andrea Kurz and Dr. Sessler?
A. People such as those.

Q. Okay. Who else would you defer to?
A. Well I think, for example, Scott -- the Hopkins -- Hopkins group, Dr. Scott and coll -- and colleagues.
Q. Okay. The Hopkins group was just a single-institution study; correct?
A. Correct. I believe so.
Q. Okay. So anyone else besides Dr. Scott?
A. I can't -- I can't off -- off the top of my head say -- say -- say, but I think it is fair to say that the original research on the subject, Drs. Sessler and Kurz are prominent.
Q. I mean you would agree with me that no one knows more about the 1996 study than Andrea Kurz.
A. That's correct.
Q. Okay. The New England Journal of Medicine. You know which one I'm referring to.
A. I know which one you're referring to.
Q. As well as Dr. Sessler; correct?
A. Correct.
(Discussion off the stenographic record.)
Q. So would it be fair to say that all the opinions you're going to give today on maintaining normothermia are based on other people's work?
A. On other people's re -- research and my

clinical experience.
Q. Okay. Well let's talk about your clinical experience. Have you looked at your patients and determined the effectiveness of maintaining normothermia and done a comparison?
A. And done -- and done a compar -- comparison? No, no, I haven't. But I look at my patient's temperature constantly and on every case.
Q. I understand that. That's part of your job; correct?
A. Correct.
Q. Okay. But have you -- you --
You've only used the Bair Hugger; correct?
A. Correct.
Q. You've never used the Mistral?
A. Correct.
Q. Have you ever used the Hot Dog?
A. Correct.
Q. Have you ever used VitaHEAT?
A. No.
Q. Okay. Have you ever used Warmtouch?
A. No.
Q. Have you ever used just warm blankets?
A. In the remote past.
Q. Okay. Have you ever used reflective

blankets?
A. No, I don't believe I have.
Q. Okay. So your -- your -- your entire experience of the effectiveness of Bair Hugger is based on the fact that you used Bair Hugger for the past 25 years.
A. Correct.
Q. Okay.
A. My personal experience is based on --
Q. You -- you -- you haven't compared it yourself with any other patient warming device; correct?
A. That's correct.
Q. You know what a patient warming device is; correct?
A. Well if you want to --
A patient war -- warming device could be many -- it could be many things.
Q. I mean there's fluid warming; correct?
A. There is fluid warming.
Q. When I'm talking about patient warming, I'm talking about something that actually warms the core of the body externally.
A. Yes.
Q. Okay. And -- and there's many different

modalities for patient warming; correct?
A. Yes.
Q. There is warming through forced air; correct?
A. Yes.
Q. Through a heating pad?
A. Yes.
Q. Just like the Hot Dog is. You understand that? It's a -- it's a -- it's a heated blanket.
A. I -- I make a distinction between a pad and a blanket, but yes.
Q. Okay. Have you heard of VitaHEAT before?
A. I have heard the name.
Q. Okay.
A. I'm not familiar with it.
Q. Do you know if 3M just -- has -- has a deal with VitaHEAT to be a distributor?
A. I am completely unaware of that.
Q. Are you aware that actually 3M is going -- getting away from using forced-air warming?
A. I don't know that.
Q. Okay. Would that surprise you?
A. Yes.
Q. You've dealt with orthopedic surgeons before; correct?

A. Yes.
Q. And dealing with total hip or total knee, they want the sterile surg -- they want the surgical site to be as sterile as possible; correct?
A. Correct.
Q. And they're against having any sort of contaminants in the sterile field; correct?
A. They would like to minimize the contaminants in the sterile field.
Q. And they dislike particles; correct?
A. I -- I don't know that.
Q. Well you have read the International Concensus; correct?
A. Yes.
Q. Have you looked at questions numbers one and two dealing with the operating room?
A. The conclusion I drew -- drew from that -- that was related to the question of -- on -- their opinion on the safety of forced-air warming.
Q. So that's the only question you looked at in the International Concensus?
A. I re -- reviewed the document, but that is the one that seemed most germane to my -- my interest. My interest is in clinical infections and not particle counts.

Q. Okay. You do understand that bacteria travel on particles; correct? Or do you not know that?
A. Bacteria can travel on particles.
Q. Bacteria can be airborne. You understand that; correct?
A. Yes.
Q. Okay. You understand that many orthopedics believe -- orthopedic surgeons believe that when an implant gets contaminated, it's through airborne contamination.
MS. LEWIS: Object to form.
A. I do not. I don't know if they believe that.
Q. Do you know what they believe in?
A. I think they were probably taught, as -- as I was, that the most likely source of contamination and infection is the patient's skin -- skin's subcutaneous flora.
Q. Subcutaneous?
A. Yes.
Q. Okay. Have you ever --
Have you read Dr. Wenzel's deposition?
A. Have I read Dr. --
Yes, I believe I have.

Q. I mean it would have been this week if you read it.
A. I'm sorry?
Q. It would have been this week if you read his deposition.
A. His --
I'm sorry. His deposition? No.
Q. Okay.
A. His expert -- expert letter in science day.
Q. Are you aware that 3M cares about particles?
MS. LEWIS: Objection, form.
A. I don't -- I --
I have no opinion what 3M cares about.
Q. Well are you aware that they funded a study doing particle tests when the Bair Hugger is on and off?
A. I'm not aware of what studies they funded.
Q. The Dr. Sessler study, you know, the guy that is well known in the field of maintaining normothermia?
A. Is there a question?
Q. Yes. Are you aware that he did a -- that 3M funded a study with respect to particle counts?
A. I'm not aware of what fund -- studies 3M funded.

Q. Well do you know that corporations fund studies?
A. Yes.
Q. Okay. You're aware of that.
A. Yes.
Q. Okay. And usually they fund studies to determine whether or not their product is safe. You understand that?
A. Usually they fund studies --
What's the question?
Q. There's many reasons to fund studies; correct?
A. Yes.
Q. One is to -- to check out the efficacy of a product; correct?
A. Yes.
Q. One is to check out the safety of a product; correct?
A. Yes.
Q. Okay. And were you aware that 3M funded a study to determine whether or not the other studies regarding increased particles or increased bubbles over the surgical site were true or not?
A. I'm not aware -- aware of which studies 3M funded and which it didn't.

Q. Well you don't look to see, you know, the conflicts of interest or anything on -- on par -- on articles to see who funded the study?
A. Well you just asked me about a specific stud -- study, and I don't recall the conflict-of-interest statement on that -- on that study or whether in fact I read that study.
Q. You were provided that study; weren't you?
A. Which study?
Q. The Sessler study.
A. How do you know that?
Q. I'm assuming that they must have provided it to you since they must have given you some information about what 3M has done.
They haven't provided it to you?
A. Whether they provided it to me or -- or not, I don't recall -- recall reading that study, and, in particular to your question, don't recall what the disclosures on that study were.
Q. Let me ask you this: I assume that 3M provided you some documents; correct?
A. 3M didn't provide --
Q. Their attorneys.
A. Oh.
Q. When I'm talking about 3M, their attorneys.

A. Yes.
Q. Let's not play games.
MS. LEWIS: They're two different things.
Q. You -- you understand that --
A. I've had no contact with 3 -- with 3M. I've had contact with Ms. Lewis and her colleagues.
Q. Well you know when you go to trial you're going to be an expert for 3M, not an expert for Blackwell Burke. You understand that; correct?
MS. LEWIS: Objection to form.
A. If you say so.
Q. I mean when you were an expert on behalf of the defense in a medical malpractice case, you were not an expert on behalf of the defendant's attorneys, you were an expert on behalf of the defendant. You understand that; correct?
A. If -- if you say so.
Q. Okay.
A. I admit I -- I am offering expert opinions that are on behalf of myself.
Q. All right. Let me ask you this: You received documents from 3M or their attorneys; correct?
A. From their attorneys.
Q. Did you read them all?

A. No.
Q. You did not read them all.
A. I did not read them all.
Q. Why not?
A. Because many -- many of them -- there were --
There were aspects of this case and discussion around this case on which I am not going to have an opinion, on which there are other experts, and so that I was selective about which materials I reviewed. There's some materials I re -- I reviewed that I determined were not meaningful in shaping my opinion about the safety of the Bair Hugger, and others that were.
Q. So you're not going to offer any opinions on any of the studies that discuss particles or helium bubbles over the surgical site?
A. To a limited degree and a limited -- and a limited sense, but I am not going to represent myself as an expert on those -- on those subjects.
Q. Well what does it mean by "limited sense?"
A. Well, for example, in the opinion -- opinion letter I point out -- point out that there are particle and bubble and airflow studies that use a mod -- model that to my eye as a practicing

anesthesiologist has very little in common with the actual operating room --
Q. Okay.
A. -- and thus its relevance to the discussion of what's important in harming my patients is limited or nil.
Q. Okay. But --
So if there's a study that was funded by 3M discussing particle counts, you don't believe you need to look at that?
A. Particle -- particle counts mean little to me compared to surgical-site infection frequency.
Q. Okay. What research have you done on surgical-site infection?
A. I have not done original research on surgical-site infection.
Q. You're not an infectious disease expert; correct?
A. Correct.
Q. You're not an orthopedic expert; correct?
A. Correct.
Q. You're not an airflow expert; correct?
A. Correct.
Q. You're not an internal medicine expert; correct?

A. Correct.
Q. Okay. You're not -- you're not an engineer; correct?
A. Correct.
Q. Okay. You're not going to opine anything -- You're not a filtration expert; correct?
A. Correct.
Q. You're not going to offer any opinions on the operating room environment; correct?
A. That --
You'll have to be more specific about that.
Q. Okay. You agree with me --
Can we agree at least that periprosthetic joint infections are caused by bacteria?
A. Yes.
Q. Okay. Anything else that could cause a periprosthetic joint infection?
A. I -- I don't -- I don't know, but it might -- there might be such a thing as a fungal infection, but that is again not my expertise.
Q. What about a virus?
A. I have never heard of that.
Q. Okay. And you agree with me that -- that -- withdraw that.
So just so I understand, you were provided

documents by 3M or their attorneys and you didn't review them all.
A. Correct.
Q. Okay. How many documents did they provide to you?
A. Prob -- probably more than a hundred.
Q. They provided you more than a hundred documents and you didn't review --
How many did you review?
A. I -- I don't -- I don't know.
Q. Why aren't they on your list of materials considered?
A. Well I reviewed -- I reviewed those, but there's a difference be -- between looking at a doc -- looking at a document and saying this is, you know, in an -- in an area that is not going to contribute to something I'm going to have -- express an opinion about and considering it in developing my opinion.
Q. Well you're discussing particles and helium bubbles, and you just told me that you reviewed the Dr. Sessler article that you -- that you seem to going to be discussing about today.
A. That I --
Q. That you said you were going to discuss -- today you said -- strike that.

Page 110

You said today you're going to discuss particles and helium and it's not representative of what's going on in the operating room; correct? The setup.

A. I -- right. I'm going to comment on the important differences between the experimental models in several -- not all -- of the -- of the studies relating to particle counts, et cetera, and my opinion that the experimental mod -- model is substantially different from a real operating room environment, which casts doubt on its relevance to the risk of infection.

Q. I understand that. My question is: What --

Do you think having people in the models, the particle or helium models, would make it better or worse for particle counts over the surgical site, if you know?

A. I -- I don't -- I don't know. But the experimental model would be more important if it -- if it had people and equipment and so forth.

Q. So you don't know, sitting here today, whether or not adding people or equipment to the operative -- operating room model would increase or decrease the amount of particles shown in these tests; correct?

Page 111

A. Correct.

Q. Okay. Do you know how many skin squames are shed in a one-hour or two-hour surgery in the operating room?

A. I don't know the number.

Q. Okay. Do you know it's in the millions?

A. If you say so.

Q. You don't know?

A. I don't know.

Q. Okay. You mentioned in your report that your infection rate for your institution is .6 percent; is that correct?

A. It was at the time I last inquire -- inquired, which was earlier this year.

Q. Earlier this year?

A. Yes.

Q. Okay. And what type of infections are we referring to?

A. Total joint arthroplasty infections.

Q. Total joint?

A. Yes.

Q. Okay. And where does that information come from?

A. The Direct -- Director of the Joint Center at the hospital.

Page 112

Q. Do you have a document that you have that -- that you get this --

A. No.

Q. -- .6 percent?

A. No.

Q. Okay. Do you know what the national average is?

A. It's in the one and -- close to one and a half percent.

Q. Okay. And that's for total hip and total knee; correct?

A. Yes.

Q. And we're talking about periprosthetic joint infections; correct?

A. Yes.

Q. And you think that your hospital, which is Wellesley --

A. Newton-Wellesley.

Q. -- Newton-Wellesley is better than the average?

A. .6 percent is better than 1.5 percent.

Q. And you're confident about those numbers?

A. I have confidence in their source.

Q. Okay. And are you as confident in that source as you are on your other sources listed on

Page 113

Materials Considered?

A. Well I'm -- I'm -- I'm hesi -- hesitating because there are items on my Materials Considered that I considered -- thought were misleading or inconclusive, so I'm not sure I would hold up that list as exclusively being items in which I have confidence.

Q. Why don't we go through Materials Considered, Exhibit 2, and why don't you mark with a highlight -- do you have a highlighter? -- all the documents that you are relying upon in formulating your opinion.

THE REPORTER: I have a red pen.

MR. ASSAAD: That's fine, a red pen works.

(Red pen handed to the witness.)

A. Now before I complete -- complete mark -- marking this, I just want to es -- es -- establish that I'm marking -- I'm marking items that contributed to formulating my opinions, which is not synonymous with agreeing or accepting the conclusions. So, for example, Legg and McGov -- McGovern have often been cited and presented to me in the campaign I referenced earlier as items that prove -- prove the risk of the Bair Hugger, so in formulating my opinions I needed to come to a -- a conclusion as to whether those

Page 114

assertions were substantiated or not and on that basis looked at that material and concluded that they did not substantiate it. So I want to understand your instruction about marking and, having described how McGovern and Legg and perhaps others fit into my creation of that opinion, whether to mark them or not.

Q. Why don't we do this then. Okay? Why don't you write the letter S next to every article under Materials Considered in Exhibit 2 that support your opinion that the Bair Hugger is safe.

A. All right. So I've des -- I've described McGovern, which purports to show that it is hazardous. It does not prove -- it does not prove that. In fact --

Q. Why don't you listen to my question, sir. Put an S next to every article on Exhibit 2 that supports your opinion that the Bair Hugger is safe. Please do.

A. I think you need to be clear about whether looking at a stud -- a -- a study that does not support the opinion that it is unsafe should be marked with an S or not.

Q. Are you saying, sitting here today, that there's no article on Exhibit 2 that supports your opinion and states that the Bair Hugger is safe?

Page 115

A. Oh, no, there -- there are -- there are many -- there are --

Q. You can mark them.

A. There are many. But what I do or don't do, for example, with respect to McGovern, I want to be very clear about what that signifies.

Q. Okay. I understand that Mc -- you disagree with the McGovern study.

A. Okay.

Q. I understand that. Okay? My question is different and it's very simple. Put an S next to every article that supports your opinion that the Bair Hugger is safe.

A. I don't want to -- I don't want to be difficult here, but if I look at a paper that has been represented as proving that it's unsafe and that it is flawed, one could say that that supports the argument that it is -- that it is safe.

Q. So if I understand you correctly, sir, you're saying that a paper -- a flawed paper that indicates a product is safe, you could logically say that the product is safe?

A. No.

Q. Okay. So why don't we put an S where it says anything that supports your opinion that the Bair Hugger is safe.

If you can't answer the question, we could go to the court and say that the -- the deponent would not listen to my instructions and put an S next to every article that supports that the Bair Hugger is safe. And I'm fine with doing that. If you don't want to answer the question, we could come back at a later date with a court order. Or if you can't answer the question, just say "I can't answer it."

Are you done, sir?

A. No, I'm still thinking about what to do about McGovern.

Q. If you want to write "Disagree with Mr. McGovern" and put a D in front of it, indicating you disagree with that, that's fine, too.

A. Okay. Maybe that's a way to get past this.

Q. All right. So you believe that the International Concensus states that the Bair Hugger is safe for use.

A. Yes.

Q. Okay. They didn't talk about further research being needed?

A. They probably did both.

Q. They never --

Did it say that the Bair Hugger is safe?

Page 117

A. Yes.

Q. You don't think they said they understand the theoretical risk posed by the Bair Hugger?

MS. LEWIS: Do you have the document so he can take a look at it?

MR. ASSAAD: He's saying it's safe. I don't have a document.

A. So I can't -- I can't quote it, but the conclusion I drew from reviewing it was that they supported the use of Bair Hugger in orthopedic implant surgery.

Q. The 1996 Kurz New England Journal of Medicine article, you believe that she states in there that the Bair Hugger is safe for use.

A. I think she says -- she states that the result of using the Bair Hugger was a reduction in surgical-site infections.

Q. You know what the issues in this case are; correct?

A. Yes.

Q. Did you understand my question when I said "safe to use," or do I need to go over the allegations in this case with you?

A. Well I think the reduct -- the reduction in surgical-site infections addresses directly the

allegation in the case.
Q. All right. So you believe that Kurz says that the Bair Hugger is safe for use; correct?
A. Yes.
Q. Okay. You agree that Kurz did not use -- It wasn't an orthopedic case; correct?
A. Correct.
Q. Okay. And you believe that Frisch indicates that the Bair Hugger is safe to use?
A. Frisch documented a small decrease in surgical-site infections.
Q. Okay. What -- Which one of these articles looked at the safety of the Bair Hugger being used in periprosthetic joint infections?
A. With respect to clinic -- the frequency of periprosthetic joint infections --
Q. Yes.
A. -- per se, there isn't such a study.
Q. Okay. So you agree with me that, sitting here today, there's -- there's not one study that indicates whether or not maintaining normothermia reduces the incidence of periprosthetic joint infections.
A. No. I would -- I would say that the

existing evidence in other settings demonstrates that, the -- risk of surgical infections, and there's no reason to believe that orthopedic surgery would be different from the surgeries that have been studied and in which a reduction in the risk of infection has been documented would be different.
Q. You -- you think a colorectal surgery where you cut the gut open and it's a dirty surgery is the same as placing an implant?
A. No, I don't think it's -- I -- I don't think the surgery is the same. Obviously, it's not.
Q. You understand that an implant deals with bacteria different than human tissue.
A. Yes.
Q. You understand that; correct?
A. Yes.
Q. I mean I know you're not an infectious disease expert, but you learned that in medical school; correct?
A. Yes.
Q. Okay. By the way, you only deal with the patient in the anesthesia or -- like pre-op, perioperatively and post-op; correct?
A. Yes.

Q. You don't deal with the patients later on when they actually get the infection; correct?
A. Correct, except for those who require additional surgery.
Q. I understand that. For an infection; correct?
A. Or dislocation or a variety of indications for reoperation.
Q. But you don't -- you don't follow your -- You don't follow the patient after they leave the post-op; correct?
A. Briefly.
Q. Okay. Okay. But whether or not they obtain a periprosthetic joint infection, there's no way for you to even know that unless they came back in and you remembered them being in the hospital before.
A. In -- in general, that's true.
Q. Okay. So with respect to -- you agree with me that there's no -- you know what -- strike that. Do you know what evidence-based medicine is?
A. Yes.
Q. Okay. And that's where you have evidence of a certain -- evidence to support a position; correct?
A. Well, to support a practice, yes.
Q. Okay. So what evidence is there, scientific

evidence -- not, "Well, look at these other studies, so the same thing must happen," but real -- real scientific evidence here that maintaining normothermia reduces the incidence of periprosthetic joint infections?
A. The scientific evidence has to -- has to do with microcirculation and tissue perfusion with oxygen and neutro -- and neutrophils being the main mechanism of host defense against wound contamination, and that physiol -- physiology is common to all surgical incisions.
Q. Give me a scientific paper that indicates that oxygenation can reduce infections on an implant that's contaminated with bacteria.
A. I'm not able to do that.
Q. Okay. Name me one peer-reviewed literature that indicates that neutrophils have an effect on fighting bacteria on a contaminated implant.
A. Well I'm -- I'm only -- I'm only going to say that the role of neutro -- neutrophils in combating bacteria is basic -- is basic science, and I can't produce the bibliography to support that, but every medical student understands that neutrophil -- neutrophils play a role in controlling --
Q. Okay.

A. -- bacter -- bacteria in surgical wounds.
Q. Let's talk about science then. How do neutrophils travel --
A. How do neutrophils travel?
Q. -- in the body?
A. In -- in the bloodstream.
Q. Okay. So you have to have circulation so the neutrophils could get to the bacteria to fight bacteria; correct?
A. Yes.
Q. Okay. So on an implant, okay, where -- if the implant is contaminated with bacteria -- -
We agree that an implant doesn't have circulation; correct?
A. The implant itself does not have circulation.
Q. Okay. So there is --
Since there's no circulation, there's no blood, therefore no neutrophils, therefore how do the neutrophils fight the bacteria?
They can't; can they? Or if you don't know, you don't know.
MS. LEWIS: Can you let him finish before you jump in?
MR. ASSAAD: I don't want him to guess,

though. He was about to guess.
A. No, it's -- it's --
Part of the answer depends on how the prosthesis is getting -- getting contaminated and whether the tissue -- whether it's contaminated from bacterial load in the ti -- in the tissues or not. If that were the case -- and I don't think you know -- you know how in any case a prosthetic gets contaminated -- then the effect of circulation, oxygen and neu -- and neutrophils in the tissues, unless -- unless you're suggesting that a bacterium from the patient's skin -- skin somehow bypasses everything and goes directly to the prosthetic material --
Q. Well that's impossible; isn't it?
A. Well I don't -- I don't know. That sounded as though it was the basis of your question.
Q. Well I mean can -- can a bacteria from the patient's skin pass through the tissue and the muscle to get straight to the implant? I mean they don't fly; do they?
A. No, but --
Well in -- in the tissues and -- and skin they are phagocytized by the neutro -- by the neutrophil, and that's why -- why those factors are important -- important even in prosthetic joint

surgery.
Q. The Frisch article you cited, you agree with me that there is no difference between patients that were maintained normothermic and were hypothermic in infection rates.
A. Can I see the paper, please?
Q. You cited it. I don't have it.
You don't have it with you?
A. Well I don't want to answer without checking the details.
Q. Okay. So you don't know the answer to that question of what Frisch did with respect to what the infection rates are; correct?
A. Frisch, there was small -- a small number of patients in the cold -- in -- in the cold group, in the hypothermic group, who had infections. I don't remember the statistical significance of that difference, and that's why I'm hesitant -- hesitating without referencing the document.
Q. You didn't cite Frisch in your report; did you?
A. No, I don't believe I did.
Q. Okay. Tissue perfusion, that's blood flow; correct?
A. Yes.

Q. Okay. And again, if the -- if the -- if the implant is contaminated with bacteria and there's no blood flow, would you agree with me that the mechanisms in which maintaining normothermia assists in surgical-site reduction don't apply?
A. I'm not able to answer that question.
Q. You can't answer that question.
A. Correct.
MR. ASSAAD: Okay. Let's take a break.
THE REPORTER: Off the record, please.
(Recess taken.)
BY MR. ASSAAD:
Q. With respect to the International Concensus that you referred to in Exhibit No. 2, did you read the entire thing?
A. I -- I scanned it.
Q. Do you know how long it is?
A. I seem to remember about 40 pages, but I'm guessing.
Q. Forty pages?
A. Yes.
Q. Okay. Now with respect to the infection rates in your hospital --
That's the Newton-Wellesley Hospital; correct?

A. Newton-Wellesley, yes.
(Exhibit 6 was marked for identification.)
BY MR. ASSAAD:
Q. Have you heard of Hospital Compare?
A. Yes, I have.
Q. And that's done by the Medic -- by Medicare; correct?
A. Yes.
Q. Do you see where on page one of Exhibit 6 it says, "National complication rate for hip/knee replacement patients was 2.8 percent?"
A. Yes, I do.
Q. See that?
A. Yes.
Q. Okay. And then under "Hospital name" it has "NEWTON-WELLESLEY HOSPITAL?"
A. Yeah.
Q. Correct?
A. Yes.
Q. And it's check marked "No different than the national rate;" correct?
A. That is what it says, yes.
Q. That's opposite of what you put in your report; correct?

A. Uh-huh.
Q. Yes?
A. Yes.
Q. Okay. Now with respect to Andrea Kurz's deposition, what did you read in her deposition?
A. There was a discussion about the differences in how she would design the study today as compared to what she did in 1996.
Q. Okay. Did you read the entire deposition?
A. I scanned it.
Q. You scanned it?
A. Yes.
Q. Okay. Did you have a limit on the amount of time that you could spend working on this case?
A. No.
Q. Were you -- were you --
Were there any constraints on how many hours you could review materials?
A. No.
Q. Okay. You -- you understand that 3M was paying your bill; correct?
A. Was paying whose bill?
Q. Your bill.
A. Yes.
Q. Okay. And 3M is a multi-billion-dollar

corporation; correct?
A. If you say so.
Q. You don't know?
A. I don't know what the value of 3M is.
Q. Okay.
A. It's large.
Q. Okay. One of the bigger companies in the United States; correct?
A. If you say so.
Q. I mean you see their products all over the place; correct?
A. Yes.
Q. Okay. They go from Post-It notes to surgical drapes; correct?
A. Yes.
Q. You use their surgical drapes; don't you?
A. I don't know.
Q. You don't know?
A. I don't know whose surgical drapes we use.
Q. You use their Bair Hugger device; correct?
A. Yes.
Q. Now with respect to Andrea Kurz's deposition, was any of the deposition highlighted that you reviewed?
A. No, I don't believe so.

Q. Was any of it marked off?
A. No, I don't believe so.
Q. Were you told to go to a certain area to read, certain line number?
A. No.
Q. Okay. Was there any other depositions that you recall scanning that you remember?
A. I recall scanning a Sessler deposition. Honestly, I can't remember whether it was in this -- in -- in this multidistrict case or in one of the earlier ones.
Q. Did you use any of the information that you obtained in the previous case, in -- in the Walton and Johnson case, in drafting your report in this case?
A. Oh, yes. Yes. I mean I thought the issues are very -- are very similar, so my thinking about Walton and Johnson in many respects relates to the questions in this case.
Q. I mean in fact you didn't -- you did not start your report from scratch for -- for this expert report, which is Exhibit 3; correct?
A. I had written -- written reports on Walton and Johnson in the past.
Q. And they are very similar to Exhibit 3; correct?

A. In -- in some respects. Obviously, this report doesn't reference anything about Walton or Johnson.
Q. I understand that. But with respect for Walton and Johnson, the -- the substance of your report is pretty much identical to what was in Walton and Johnson.
A. Right, it is similar.
Q. Very similar. Do you agree?
A. You want to define "very" -- "very similar?" It's similar.
Q. I mean you almost have the same headings.
A. That may be the case. I don't recall the Walton and Johnson letters at this time.
Q. Did you review what -- the Walton and Johnson expert reports in preparation for today's deposition?
A. No. I reviewed this one.
Q. Okay. Did you review Walton and Johnson's reports before you wrote this report, Exhibit 3?
A. Oh, yes. Yes.
Q. And in fact you just opened up the report and just made changes to it; correct?
A. Very -- very -- very likely.
Q. Okay.

A. It was months ago, so I'm not sure exactly what -- what I -- what I did.
Q. It was only two months ago, sir, --
A. It was only two --
Q. -- that you wrote this report.
A. That I submitted this report, yes.
Q. I mean it wasn't years ago, it was only two months ago.
A. No. Okay. So whether I copied -- copied or pasted or edited or retyped --
Q. Okay. Now how much time did you bill in Walton and Johnson?
A. I -- I don't recall.
Q. More than 20 hours?
A. Probably.
Q. And you used that work, the stuff that you reviewed and you learned in Walton and Johnson, in -- in your expert report in this case; correct?
A. Correct.
Q. And you didn't submit any of those invoices to us that you have in Walton and Johnson; did you?
A. Correct.
Q. Did you provide those invoices to defense counsel?
A. No.

Q. Why not?
A. I wasn't asked to.
Q. Well wasn't that part of the subpoena, all the invoices in the Bair Hugger litigation?
A. Well it depends --
I -- I don't recall the -- the wording, but at least when I was thinking about it I was thinking about the current action, the current action, and thinking of that as distinct from the others.
Q. Did you ask anyone -- did you ask anyone whether or not this included the invoices for Walton and Johnson?
A. Yes, I did.
Q. Okay.
A. And I was told to limit -- limit the invoices I produced to this -- this case.
Q. Okay.
MS. LEWIS: Counsel, we made our objections -- which you guys have -- on the subpoena and with respect to the scope of your subpoena and time.
Q. Do you know whether or not you billed more than 20 hours in Walton and Johnson combined?
A. I -- I seem to recall that that's probably the case. I don't know how many hours exactly.

Q. Okay. Do you recall receiving over a hundred articles in Walton and Johnson from Greenberg Traurig?
A. Yes.
Q. Okay. Do you recall receiving hundreds of pages of internal documents from Greenberg Traurig, 3M documents?
A. I think there were 3M documents in the materials that they sent.
Q. Did you review those?
A. I looked -- looked at them and determined that they would not be helpful to me in formulating my opin -- my opinions on this case.
Q. So if there were internal documents at 3M that indicated that the Bair Hugger increases pathogens over the surgical site, that would not pertain to your opinions in this case?
A. My opinions in this --
MS. LEWIS: Objection to the form.
A. My opinions in this case are principally focused on clinical outcomes.
Q. Okay. So is it fair to say that your sole opinion in this case -- or your -- your opinion in this case is not whether the Bair Hugger is safe, just the clinical outcome of maintaining normothermia.

Page 134

A. No, that's not correct.
Q. Okay. So if your opinion is whether or not the Bair Hugger is safe for use, wouldn't internal testing be relevant to determine the safety of the Bair Hugger device?
A. Well intern -- internal testing, to the extent that it address -- addresses particles, air bubbles and other surrogates, are neither my expertise nor the basis on which I would make a clinical judgment about choosing to use the Bair Hugger or not.
Q. So if there were documents that exist that indicate that the Bair Hugger increases the bacterial load over the surgical site, that would be irrelevant to the safety of the Bair Hugger to you?
MS. LEWIS: Objection, form.
A. A, I am not qualif -- qualified to draw the connection between that finding and the risk of using the Bair -- Bair Hugger, and this is, you know, a very high -- high-volume operation and the rate of surgical infections with it is amen -- amenable to study. So my expectation, what I am looking for and what I've been looking for ever since I first heard allegations of its hazard, has been documentation that more pa -- more patients have surgical-site infections when Bair Huggers are used than when it is not used. I don't

Page 135

believe such a thing exists.
Q. Okay. Do you know the difference between a surgical-site infection and a periprosthetic joint infection?
A. I'm -- I'm sorry?
Q. Do you know the difference between a superficial -- a surgical-site infection and a periprosthetic joint infection?
A. Well surgical-site infection is kind of an all-encompassing term, of which periprosthetic joint infections is one variety.
Q. Are there any allegations that you're aware of that the Bair Hugger increases the incidence of superficial surgical-site infections?
A. I -- I think the -- the action is about peri -- periprosthetic joint -- joint infections.
Q. Do you know how many bacteria or CFUs are needed to cause a periprosthetic joint infection?
A. No.
Q. Do you know if it's more or less than a superficial surgical-site infection?
A. No.
Q. Are you aware -- strike that.
You agree with me that a study could be conducted to determine whether or not the Bair Hugger

Page 136

increases the incidence of periprosthetic joint infections; correct?
A. Yes, I believe that's true. But study -- study design is not my area of expertise.
Q. Okay.
A. But all right.
Q. Your area of expertise is to just criticize the literature in this case; correct?
A. My area of expertise is making clinical decisions about caring for my patients.
Q. And your clinical decisions are based on literature that you have read; correct?
A. Yes.
Q. Okay.
A. Well let -- let me --
Q. Yes.
A. Let me, if I may, continue.
Q. Sure.
A. My clinical decision-making is based on -- not only on literature I have read but, when you look at the list of materials, the systematic analyses that groups like ECRI and NICE -- and NICE and others have done, and those groups, because they are thor -- thorough, impartial and have advanced methodological skills, the conclusions they draw from their analyses

Page 137

of the existing science is very persuasive.
Q. Okay. Well let's talk about ECRI then. Are you aware of the interact -- interactions ECRI had with 3M and Arizant regarding this issue?
A. No.
Q. Okay. Do you know that ECRI interviewed -- interviewed people at 3M and Arizant?
A. I don't know that.
Q. Okay. Do you think --
If you found out that the information provided by Arizant and 3M was inaccurate to ECRI, would that affect your decision?
A. Yeah, I --
You'd have to be more -- more specific about what the inaccuracies were.
Q. Well do you know that one of the goals of 3M and Arizant was to prevent ECRI from doing any type of study?
MS. LEWIS: Objection to the form of the question.
A. Right. So my understanding of what --
Q. It's a simple "yes" or "no." Did you know that?
A. No. I don't know whether that's true or not.

Q. Okay. So you've never heard that before; correct?
A. I have not.
Q. Because you haven't looked at the internal documents that 3M has; correct?
A. Correct.
Q. Okay. If that was true, would that affect your opinions in this case?
A. If it were true that 3M tried to stop ECRI from doing a study?
Q. Yes.
A. Well what they tried to do or didn't try to do isn't really ger -- germane, it's what ECRI did or didn't do in the end.
Q. I understand that. But would it affect your decision with respect to the responses that 3M and Arizant provided to ECRI regarding the safety of the device?
A. I'm not -- I'm not -- I'm not --
Would it affect my opinion about 3M and Arizant, is that the question?
Q. I think --
Yeah.
A. I don't feel as though I particularly have an opinion about 3M and Arizant's be -- behavior with

respect to ECRI. As I said, what ECRI did, which is not a study of the -- the safety of the Bair Hugger in the sense of original investigation --
Q. They just reviewed the literature.
A. It is a systematic re -- review, something like a meta-analysis of the -- of the literature.
Q. I wouldn't call it a meta-analysis. They just reviewed the literature.
A. Okay.
Q. Correct?
A. Okay.
Q. Do you recall any meta-analysis done by ECRI?
A. No. A systematic review.
Q. Okay. Something that anyone could do; correct?
A. Well I -- I -- I think the --
When I refer to the methodological expertise, I think that they bring to -- bring to the table the ability to critically eval -- evaluate the scientific validity of the material they're looking at, and I'm not sure that everybody could do -- could do that. So I think the answer is no, not everybody could do what ECRI did.
Q. You do understand --

Do you know what a 510(k) clearance is?
A. I -- I -- I heard the term.
Q. Okay. You understand that, with respect to the safety of medical devices or even drugs, that the government relies on information provided by the manufacturer?
A. If you say so. I have no experience in the --
Q. Okay.
A. -- 510(k) process.
Q. Okay. And you're not going to be providing any opinions on warnings since you don't understand the FDA process; correct?
A. Well I'm not going to give an opinion about what the FDA requires or not -- doesn't require. I can give -- give an opinion about the warnings that I -- I see as a user of the -- of the device if you have questions about that.
Q. Well what is your expertise in medical device warnings, if any?
I'll withdraw the question. Have you yourself --
You've never created a medical device; correct?
A. Correct. Correct.

Q. You've never been advised on --
You've never been consulted on what warnings should be on a medical device; correct?
A. Correct.
Q. You've never actually written warnings in your entire life; correct?
A. Correct.
Q. Okay. You -- you -- you don't know --
You've never had any discussions with respect with orthopedic surgeons and whether or not they look unfavorably with respect to particles; correct?
A. Correct.
Q. You're not an expert in airborne contamination; correct?
A. Correct.
Q. You're not an expert in infectious disease; correct?
A. Correct.
Q. You're not an expert in -- in -- in forced-air warming; correct?
The device itself.
A. Correct.
Q. Okay. Do you even know how much heat comes out of the Bair Hugger?

Page 142

A. I can only reflect on having sat next to one -- next to one for thousands of hours.
Q. Do you feel the heat coming out?
A. No.
Q. You never feel the heat coming out.
A. Only when I'm under -- under the blanket.
Q. So what does sitting next to -- next to them indicate about how much heat is coming out of the Bair Hugger?
A. Not very much.
Q. Do you think it's warmer -- warmer -- Do you think the temperature of the air coming out is warmer or cooler than the body temperature?
A. Are you talking -- talking about coming out of the blanket?
Q. Yes.
A. Yes, it's warm -- it's warmer than the blank -- than the body temperature.
Q. Do you know what temperature?
A. It's -- On high I think it's 42 degrees.
Q. You think it's 42 degrees?
A. Yes.
Q. Okay. And you've had a thousand hours

Page 143

working on the Bair Hugger -- working with the Bair Hugger?
A. At least. At least.
Q. Okay. And you're the one that controls the Bair Hugger device?
A. Yes.
Q. Do you turn it on and off?
A. I do.
Q. And you believe it's 42 degrees.
A. I think it's high -- high -- high, medium and low, but I think the high corresponds to 42 degrees.
Q. Okay. And have you ever taken apart a Bair Hugger?
A. No.
Q. What are plaintiffs' allegations with respect to the mechanism of injury that the Bair Hugger causes?
A. There -- there are multiple: increase -- increases particles, increases turbulence, increases temperature in the vicinity of the -- of the -- of the wound, disrupts laminar -- laminar flow. You know, those -- those are the ones that immediately come to mind.
Q. Where do you think the heat goes that comes

Page 144

out of the Bair Hugger?
A. The heat goes, coming out of the Bair Hugger blanket --
Q. Where does it go?
A. Generally, with an upper body blan -- blan -- blanket, the heat emanates at the patient's head.
Q. Emanates at the patient's head.
A. Yes.
Q. So how many holes does the Bair Hugger blanket have?
A. How many holes?
Q. Yeah.
A. It has many -- many small perforations.
Q. Okay. And it comes out at the patient's head. What percentage of the air comes out at the patient's head?
A. I don't know what percentage at the patient's head.
Q. Do you see the plastic sheet flapping that goes -- covers the head?
A. Occasionally, yes.
Q. Occasionally?
A. Yes.
Q. What does "occasionally" mean?

Page 145

A. Sometimes I observe it flapping and sometimes it doesn't appear to be flapping.
Q. Okay. So what percentage of the time would you see the -- the plastic sheet that covers the patient's head flapping?
A. I have -- I've never -- never calculated that percentage.
Q. Well can you give me a rough estimate?
A. Not really.
Q. More than 50 percent of the time?
A. I'm not going to give you an estimate.
Q. Why not?
A. Because I don't -- I'm not guessing.
Q. Okay. So you think -- you think the majority of the air comes out at the patient's neck and head.
A. The -- the upper -- upper body, yes.
Q. Okay. So --
A. The rest of the blanket is tightly secured, so that's the path of least resistance.
Q. Okay. And why do you think it's tightly secured?
A. To gain maxi -- maximum benefit from the use of the blanket.

Q. You don't -- you don't think any air could pass down the arm --
A. Of course, of course, of course it can.
Q. Okay.
A. But it is -- the --
The area around the head -- head and neck is more loosely applied than it is around the arms and does not have the -- all the surgical drapes on top of it in the same way that the arms do, so whatever air is emanating is most often felt there.
Q. Okay. What basis do you have, scientific basis, that most of the air comes out at the head and neck?
A. I have, as I said, thousands of hours of using the device.
Q. Yeah. And you believe that the top temperature is 42 degrees; right?
A. Yes.
Q. Okay. And you also believe that your infection rates in your hospital are .6 percent; correct?
A. That's what I was told.
Q. Okay. But that's not correct; is it?
MS. LEWIS: Objection to the form of the question.

A. I am not sure of the basis of the statistics that you've -- you've given me, so I don't know which one is correct.
Q. Well you've heard of Hospital Compare; correct?
A. I have heard of Hospital Compare.
Q. And that's based on reporting from the hospitals; correct?
A. Presumably, yes.
Q. Okay. The fact that Andrea Kurz cooled her patients during the 1996 study, does that affect your opinion of that study?
The control group, that she cooled the control group.
A. No. I think her study is important.
Q. Okay. So the mere fact that the control was actually cooled, which is not done in the real world, okay, has no effect on the effects of the statistics produced in that paper?
A. I think the statistics are the statistics.
Q. Yes. A patient that's cooled and a patient that's warmed; correct?
A. Right.
Q. Okay. What -- what's the -- what's the infection-rate drop, if any, if a patient is placed in

warm blankets compared to forced-air warming?
A. I'm sorry. Say again.
Q. What -- what -- what --
In a colorectal surgery, if a patient was just using warm blankets, like heated blankets, as compared to forced-air warming, would there be a reduction in surgical-site infections, if you know?
A. Well what I want to say is that warm blankets are less effective in restoring core temperature than active warming, and restoring core temperature reduces the rate of -- of infection.
Q. Would you agree with me that warming blank -- warm blankets are more effective than cooling a patient?
A. I don't know.
Q. You don't know?
A. I don't know.
Q. So if a patient went from 36 degrees to 35.5 degrees, do you know what the effects would be on surgical-site infections in colorectal surgery?
A. To -- to quantify that change?
Q. Huh?
A. To quantify -- to quantify the impact of that change in temperature, is that what you're asking?

Q. If the patient is 35.5 degrees, is that going to increase the incidence of surgical-site infections?
A. As compared to normothermia.
Q. As compared to 36 degrees. If you know.
A. In -- in theory, but I don't -- I don't know.
Q. Well could we --
Well you don't like theory because there -- there's a theor -- there's a theoretical risk according to the International Concensus that Bair Hugger increases the risks of infections; correct?
MS. LEWIS: Objection to form.
Q. So you disregard that theory, so let's not talk about theories. Let's talk about facts and science.
A. Okay. So I don't -- I don't -- I don't know what the incremental change in infection risk from 35.5 to 36 is.
Q. If any.
A. If any.
Q. Okay. What about 35 degrees compared to 36 degrees Celsius?
A. Well the only thing I would -- I -- I would say, that hypo -- hypothermia increases the risk of

Page 150

infection and other periprosthetic compli -- complications, and I don't know that I've seen that it is, so to speak, dose-dependent, and -- and that is, is the relationship between temperature and infection risk linear or have some other relationship. I don't know.

Q. Well with respect to surgical-site infections, you're relying on the Kurz study; correct?

For perioperative warming.

A. I am relying on the Kurz study and oth -- and others.

Q. What others?

A. Mell -- Melling, Scott. So there are number -- a number of studies, more recent ones, that seem to come to the same conclusions as -- as Kurz did in '96.

Q. So you're talking about Melling and Scott; correct?

And we're talking about wound infections here; right?

A. Correct.

Q. Okay. So Melling and Scott. Anything -- And Kurz; correct?

A. Yes.

Q. What else, sitting here today?

Page 151

A. We talked a little bit earl -- earlier, again -- again I need to look at the statistics in Frisch, but there was a diff -- a difference in the frequency of infections in those patients.

Q. Well you're --

You hold yourself out as an expert in maintaining normothermia; correct?

A. I hold myself out as a -- yeah, somebody who has made that a clinical goal.

Q. That's not my question of making a clinical goal.

A. Yeah.

Q. Okay? I -- I make many goals in my life but I'm not an expert in. Okay?

My question is: Do you consider yourself an expert in the risks and benefits of maintaining normothermia?

A. Yes.

Q. Okay. So you should know the studies that you're going to rely upon because you yourself have done no research on the issue; correct?

A. I have, as I said previously, heavily re -- relied on systematic analyses of groups expert in summarizing the available findings, such as ECRI, NICE, and the physician consortium and the others I've

Page 152

identified.

Q. Okay. And they're relying on Kurz, Melling and --

A. Well they're -- they're -- they're look -- they're looking at McGovern and Legg and everybody who has published on this. Right?

Q. Well here -- here's the unfortunate thing, sir. Okay? You've been designated an expert in this case as to maintaining normothermia; correct?

A. I -- that's why --

Q. Okay.

A. That's why I'm here.

Q. So you can't rely on other groups that have done reviews --

A. No, I -- I disagree with that. I certainly can.

Q. Okay. So you're going to rely on -- on -- on other people, so I could just read what they say and that's what you're going to say.

A. To a -- to a degree.

Q. Okay.

A. They have very -- they have --

They are very persuasive in my decision-making.

Q. Okay. So sitting here today, besides Kurz,

Page 153

Melling, Scott and -- and Frisch, are you aware of any scientific literature that's not a review that discusses the -- the relationship between maintaining normothermia and surgical-site infection?

A. That discusses --

Well yes. Mc -- McGovern purports to do -- to do that.

Q. McGovern?

A. He purports to discuss the relationship of normothermia and surgical-site infection.

Q. No. He discusses the relationship between the mode of maintaining normothermia and periprosthetic joint infection.

A. Well why -- why are we using Bair -- Bair Hugger if not to maintain normothermia?

Q. Well does he talk about the patient --

Does he take any temperature of -- of the patient, measurement -- measurements of the temperature of the patient?

A. Okay. Fair -- fair enough. He's discussing the hazards --

Q. Yes.

A. -- of warming the patient to achieve -- achieve the goal of normothermia. Fine.

Q. I'm talking about --

Page 154

A. Okay.
Q. I'm talking about maintaining normothermia.
A. Fine.
Q. And so you're going to rely on Kurz, Melling, Scott and Frisch today.
And feel free to look at Exhibit 2.
A. Yes. Yeah.
Yes, I'll -- I'll qualify Melling in that it is mostly relevant to establish the safe -- the safety of Bair Hugger and achieving norm -- normothermia, because while many -- well infections broadly sta -- broadly stated were dramatically reduced, there was no difference in the groups with respect to surgical-site infect -- in -- infections, which says -- says to me that sepsis, which probably includes surgical-site infections in many instances where there was a dramatic reduction and all the other clinical outcomes were im -- were improved, so that one is a little different from the others.
Q. You're talking about Melling?
A. No, I'm sorry, Scott.
Q. Scott. Okay.
A. Yeah.
Q. Are you relying on Scott today, that

Page 155

maintaining normothermia reduces the incidence of surgical-site infections?
A. It reduces the in -- incidence of infectious complications of all -- of any kind.
Q. That wasn't my question, sir.
A. Correct. No difference in surgical -- surgical-site infections to the extent that the study methodology would distinguish between those infections and the others.
Q. Well they actually did distinguish it; didn't they?
A. Well they said they did.
Q. Have you looked at the data?
A. I -- I looked at the source of the data, which is administrative data, which depends on -- on coding for the purpose of -- of billing.
(Exhibit 7 was marked for identification.)
MR. ASSAAD: No. I'm sorry. I gave you the Sun article. We'll get to this in a second. Sorry.
BY MR. ASSAAD:
Q. Are you familiar with this article, sir, the Sun article?
A. No, I don't think I am.
Q. With Dr. Sessler and Andrea Kurz?

Page 156

A. No, I don't think I am.
Q. Okay. Why don't you look at the conclusions, tell me if you agree with this.
A. Which one?
Q. "Even in actively warmed patients, hypothermia is routine during the first hour of anesthesia." Do you agree with that statement?
A. Yes, temperatures drop in the first hour of anesthesia.
Q. Okay.
(Exhibit 8 was marked for identification.)
BY MR. ASSAAD:
Q. Exhibit 8 is titled "Compliance with Surgical Care Improvement Project for Body Temperature Management (SCIP-10) Is Associated with Improved Clinical Outcomes" by Andrew V. Scott et al. Is this the article you're referring to?
A. Yes, it is.
Q. Okay. Let's turn to page five. Under "Wound infection" --
That's a surgical-site infection, correct, on -- on Table 4?
A. Yes. Yeah.
Q. Do you agree with me that SCIP non-

Page 157

compliant has a lower infection rate than SCIP compliant?
A. Not in a significant way -- way.
Q. That wasn't my question.
A. Yes.
Q. It's lower; correct?
A. The raw -- the raw numbers are lower.
Q. Okay. It's not statistically significant --
A. So I would characterize it as no difference.
Q. Okay. And this is 2015; correct?
A. Correct.
Q. Published in Anesthesiology; correct?
A. Correct.
Q. And you subscribe to Anesthesiology; correct?
A. Yes.
Q. And you believe that's an authoritative journal; correct?
A. It's a reputable journal.
Q. You -- you think it's authoritative.
A. I believe it has -- has a robust editorial process.
Q. And you've cited to this article in your Materials Considered; correct?
A. Yes, I have.

Page 158

Q. So you believe it's authoritative.
A. I believe -- I -- it is --
It is there because it influenced my opinion on the safety of the Bair Hugger.
Q. Okay. Well it doesn't really talk about the safety of the Bair Hugger, it talks about the efficacy of the Bair Hugger.
A. No. I think the frequency of the complications stud -- studied goes directly to the question of safety.
Q. Is there anything in Scott that discusses whether or not the Bair Hugger contaminates the sterile field through either being contaminated itself or by disrupting laminar flow?
A. No. That's the beauty of the Scott paper, is that it talks about clinical outcomes and what matters to patients.
Q. Well the beauty is, then, that there's no difference in wound infections between maintaining normothermia and not maintaining normothermia; correct?
A. Normothermia in this study was maintained -- maintained with the use of the Bair Hugger. There being no difference in wound infections and a dramatic difference in all infections, in addition to the other

Page 159

complications, tells me that it is a safe -- a safe device and is good practice to -- to use.
Q. What -- what percentage of patients that have peri -- total knee or total hip actually have -- get sepsis?
A. I don't know.
Q. Okay. What -- what percentage of patients that have total hip or total knee actually have a drug-resistant infection?
A. I did not -- I don't --
I don't know.
Q. Okay. What percentage of patients have some sort of an ischemic cardiac -- cardiovascular event, of total hip or total knee patients, arthroplasty patients?
A. I don't know.
Q. Okay.
A. I don't know that they are different -- different from this diverse group of surgical patients.
Q. You agree with me that this article does not talk about whether or not the Bair Hugger contaminates the sterile field by its use.
MS. LEWIS: Objection, form.
A. It dis -- it discusses the out -- outcomes

Page 160

that would make that finding relevant but doesn't discuss the contamination of the surgical wound -- wound directly, only the clinical marker of that event.
Q. Well it --
I mean you believe maintaining normothermia reduces the risks of surgical-site infection; don't you?
A. Yes.
Q. You do. But this study says the opposite with respect to wound infections; correct?
A. No, it says there's no difference.
Q. Well SCIP non-compliant means either, one, they --
Well SCIP non-compliant means they didn't use any type of maintain -- forced-air warming or patient warming.
A. Or didn't achieve the target temperature.
Q. No. You could still be SCIP compliant as long as you --
As long as you're using a forced-air warming --
A. Correct.
Q. -- device you're SCIP compliant; correct?
A. Right, but --

Page 161

And if you don't use it and meet the target temperature, you're also SCIP compliant.
Q. Yes. So the ones that they did not --
SCIP non-compliant means that you weren't at the target temperature and you did not use a patient warming device; correct?
A. Correct.
Q. Okay. So we could agree, for the SCIP non-compliant, no patient warming device was used.
A. Or a patient warming device was used -- was used --
No. I'm sorry. Correct.
Q. I'm correct.
A. Okay.
Q. Right?
A. You are.
Q. Okay. So we have here on page five 1,240 patients that no patient warming device was used on; correct? Correct?
A. Correct.
Q. Okay. And then you have the SCIP compliant, which has 44,000 patients that warming was used; correct?
A. Correct.
Q. And it was forced-air warming in this case;

correct?
A. Yes.
Q. Now since you believe that forced-air warming or patient warming reduces the incidence of surgical-site infection, why is there no difference for wound infections?
If you know.
A. Well I don't -- I don't know, I don't know, but the -- the size of the two -- two groups may produce a statistical effect that produces this. But as I said, this informs my opinion, because if forced-air warming were dangerous, I would expect to see the SCIP compliant group have a substantially higher rate of wound infection and other -- and other infectious complications than the group in which it wasn't used, --
Q. Did you ever think --
A. -- and that is not the case.
Q. Did you ever think of this possibility, sir, that maintaining normothermia reduces the incidence of wound infection but it's been offset because of the risk of the Bair Hugger and that's why you get equal numbers? Isn't that -- isn't that a possibility?
A. Well if this were the on -- were the only study in existence addressing this and the others

didn't -- didn't exist, that would -- might be an attractive theory to explain the result.
Q. And you need further research; correct?
A. Well I have several -- several other studies that show a reduction in infections.
Q. Okay. But with respect to Sun, that -- if that -- that's a possibility --
A. We're talking about Scott; right?
Q. Or Scott. That's a study that you would maybe require further research to determine whether or not the Bair Hugger is increasing the infection rate but at the same time reducing the wound infection rate so you get a non-statistically significant between use and non-use. It's a possibility; correct?
A. I -- I suppose it's a possibility.
Q. Okay. So what study do you want to talk about next, Kurz or Melling?
A. You're -- you're asking the questions.
Q. Okay. Let's talk about Melling. Is Melling perioperative warming?
A. Melling is perioperative warming.
Q. Is that what you believe?
A. It's perioperative warming.
Q. Are you sure about that?
A. Yeah.

Q. Okay. And you believe Melling supports the safety of the Bair Hugger perioperatively.
A. Well the Bair -- in this --
In this case, this is about hypother -- hypothermia and the frequency of infections in clean -- in clean surgery. There were two modalities used, neither in the operating room, but the patient's temper -- temperatures or the surgical-field temperature -- temperatures in some of the cases was managed with local warming or body -- body warming perioperatively.
Q. You understand that Melling is -- is preoperative warming.
A. Yes.
Q. Okay. When --
A. And when you said -- when you said "perioperative warming," in my mind that includes preoperative.
Q. Okay.
A. But the point here is the effect of warming.
Q. You agree with me that prewarming lasts for about three hours based on the science.
A. Yeah. I don't -- I don't know about that, but these patients --
Q. Okay.

A. The warmed patients were not surprisingly warmer.
Q. Melling wasn't --
Bair Hugger wasn't used from incision to incision.
A. Correct.
Q. Okay. So Melling was not used intraoperatively; correct?
A. Correct.
Q. Okay. So Melling wouldn't indicate whether or not the use of Bair Hugger would contaminate the sterile field because the Bair Hugger wasn't used intraoperatively; correct?
A. Correct. Melling speak -- speaks to the importance of normothermia in reducing the risk of surgical infection.
Q. The effect of prewarming on normothermia.
A. Norm --
Q. Okay.
A. Normothermia.
Q. Okay. Let's talk about Kurz. Do you recall reading any -- anything in the deposition of Andrea Kurz where she stated that, with -- let me get the exact words --
MS. LEWIS: Are you going to have a copy for

Dr. Hannenberg?
MR. ASSAAD: No.
MS. LEWIS: Okay. I just want the record to so reflect.
MR. ASSAAD: Next time maybe if you instruct your witnesses to come with information so they can answer questions --
MS. LEWIS: Since they don't know what question you're going to ask, --
MR. ASSAAD: That's why they should bring everything.
MS. LEWIS: -- they're supposed to guess?
MR. ASSAAD: I mean you go to trial with all the files; don't you? I don't know if you go to trial, but if you do, you should bring all the files.
Q. So do you recall when Dr. Kurz indicated that Kurz would not meet current research guidelines and -- and scientific reliability in -- in -- in today's world?
MS. LEWIS: Dr. Hannenberg, if you remember, that's fine; if you don't, if you want to see the document --
THE WITNESS: Seeing the document would be helpful.
(Exhibit 9 was marked for

identification.)
MR. ASSAAD: Why don't we take a break for lunch and we'll get back to this when we get back.
THE REPORTER: Off the record, please.
(Recess taken.)

AFTERNOON SESSION
BY MR. ASSAAD:
Q. Are you ready to continue, doctor?
A. Yes, I am.
Q. Before I get to the Kurz deposition, we were talking about some of the articles that support your opinion that maintaining normothermia reduces the incidence of infection. You -- you haven't been provided any internal documents or minutes regarding conversations with Andrea Kurz or Dr. Sessler within 3M; have you?
A. I don't believe so.
Q. Okay.
(Exhibit 10 was marked for identification.)
BY MR. ASSAAD:
Q. Exhibit 10 is a document provided to the plaintiffs from defendants talking about the Global Patient Warming Advisory meeting on October 18th, 2012. Do you see that as the heading?
A. Yes, I do.
Q. And you see that the board members are Dan Sessler, Pedro Barbieri, Andrea Kurz, Claude LaFlamme and Berthold Bein. Do you see that?
A. Yes, I do.

Q. Do you know those individuals?
A. I know Sessler and I've met Kurz; otherwise, no.
Q. Okay. And at the bottom you see there's Bates numbers there where there's like numbers 3MBH?
A. 3MBH, yes.
Q. Okay. I'd like you to turn to page 3MBH01242445.
A. 2445. Has a 6 on the top right?
Q. Yes.
A. Uh-huh.
Q. And on the top -- top it says "Kurz 1996 SSI paper limitations: only 200 patients, mostly superficial infections with few clinical consequences (we should focus on deep tissue organ SSIs), the factor of 3 risk increase is not plausible (30 percent or so is more likely)."
Did I read that correctly?
A. Yes.
Q. Were you aware that most of the infections documented in the 1996 Kurz study in the New England Journal of Medicine dealt with mostly superficial infections with few clinical consequences?
MS. LEWIS: Do you have a copy of the Kurz study?

Page 170

A. Well I am aware -- aware that it didn't involve prosthetic infect -- infections, but whether it was superficial or deep -- or deep tissue or organ space, I don't recall.
Q. We talked about clinical outcomes --
A. Yes.
Q. -- regarding maintaining normothermia. And that's important, isn't it, clinical outcomes? Correct?
A. Yes.
Q. And here's a document in which -- a meeting in which Kurz attended that said most -- "mostly superficial infections with few clinical consequences" were the infections recorded in the Kurz paper. Does that change your opinion of the -- the strength of the Kurz paper?
A. I think the Kurz paper still is a reli -- reliable piece of information about the effect of normothermia on surgical in -- infections.
Q. Do you think -- do you think maintaining normothermia reduces the incidence of infection in colorectal surgeries by a multiplier of three in today's world?
A. I have no basis on which to -- to say --
Q. Okay.

Page 171

A. -- in today's world what the result of such a study would be.
Q. I mean you agree that there are infections out there that really have no clinical consequence.
A. I -- I'm -- I'm not sure about that. I think to the patient infections have clinical consequences.
Q. That wasn't my question. There --
There are infections out there that have no clinical consequences.
A. No.
Q. You disagree with that?
A. I disagree with that.
Q. Okay. So there are infections there that could be a superficial wound infection, I put some antibiotics on and I'm fine in a day?
A. There could be infections like -- like that. But among the infect -- infections identified in -- in the study, I don't think Kurz was saying that they were all superficial infections.
Q. Right here, "mostly superficial infections" --
A. Mostly --
Q. -- "with few clinical consequences."
A. "Mostly superficial infections" --

Page 172

Q. Okay.
A. -- "with few" -- yeah.
Q. And it actually goes on and say "(we should focus on deep tissue organ SSIs)."
MS. LEWIS: Objection to the form of the question.
Q. That's what it says there; right?
A. That's what it says there.
Q. Okay. And this was a meeting in which Andrea Kurz was present, and you agree with that.
MS. LEWIS: Objection to the form of the question.
A. That's what it says.
Q. And the reason why you should focus on deep tissue organ SSIs is because those are clinically significant; correct?
A. I would say they are more clinically significant.
Q. Okay. She goes on, "...the factor" -- or the paper goes on, "...the factor of 3 risk increase is not plausible..." You have no reason to agree or disagree with that; correct?
A. Correct.
Q. Okay. The "Melling paper" -- next line -- "seriously flawed: only 420 low risk patients,

Page 173

infection was not defined, core temperature not recorded(!)"
Were you aware of the significant and serious flaws of the Melling paper?
A. I think the Melling paper is also infor -- informative despite -- despite these comments.
Q. Okay. But you would agree with me, especially with the Kurz paper, that Andrea Kurz knows more about her paper and the limitations than you do.
A. She does.
Q. Okay. Let's go to the deposition of Andrea Kurz. I'd like you to turn to page 179. If you look at page 179 of Andrea Kurz's deposition, which is marked as Exhibit No. 9, line 16:
"Question: In today's scientific standards, there is no reliable evidence that supports that maintaining normothermia reduces the incidence of infection.
"Answer: That is correct."
Do you agree with that statement and answer?
A. No.
Q. Okay. So you disagree with Andrea Kurz.
A. Yes.
Q. Okay.
MS. LEWIS: I'm sorry, tell me what page

Page 174

number we are again.
MR. ASSAAD: 179.
MS. LEWIS: Okay. Thank you.
Q. So Andrea Kurz, who has done more research than most people in the world on maintaining normothermia and its effects, you, as a person who's never done research on maintaining normothermia, disagree with Dr. Kurz.
A. Yes.
Q. Okay.
A. I disagree with that -- with that statement. I'm sure there are many things Dr. Kurz has said that I agree with, but with respect to that statement, yes, I disagree.
Q. You disagree with that statement. Okay.
A. I disagree with that statement.
Q. And what's your basis to disagree with that statement?
A. Because her research is not the -- the only evidence that addresses this -- this question, and we've already talked about oth -- others and other more recent research.
Q. Well, with respect to surgical-site infections, what valid scientific evidence is there that indicates that maintaining normothermia reduces

Page 175

the incidence of surgical-site infections?
A. Kurz, Melling.
Q. Okay. Anything else?
A. The --
No, I would say I would point to those.
Q. Okay. So you disagree with Dr. Kurz's opinions on her own study that you're citing to support maintaining normothermia reduces the incidence of infections.
A. Well I'm not --
So this statement of hers is conditioned by the phrase "In today's scientific standards," and I don't know what she means by -- by that.
Q. Well if you read the deposition --
A. Or that's your -- that's your ques -- that's your question. I'm not sure what -- what you mean by that.
Q. And you've had a copy of this deposition; right?
A. I had a copy of this deposition.
Q. Okay. And you had a chance to read it; correct?
A. I did.
Q. Okay. And you were never provided a -- a copy of Exhibit No. 10; were you?

Page 176

A. Which is Exhibit No. 10?
Q. The minutes.
A. I don't believe I was, --
Q. Okay.
A. -- no.
Q. Were you ever informed that Dr. Sessler indicated in 2016 saying that knowing what he knows now, that he would have never published the 1996 Sessler paper with Dr. Kurz?
A. I'm not aware of that statement.
Q. Would that affect your opinion with respect to the quality of the 1996 study?
A. I -- I -- I don't know why he said -- why he would say that.
Q. So you're not aware that he's made that statement in the past; correct?
A. I am not aware of that.
Q. And if he did make that statement, would it change your opinion?
A. Again, it would depend why he was saying it, what he was thinking.
(Exhibit 11 was marked for identification.)
BY MR. ASSAAD:
Q. What's been marked as Exhibit 11 is an

Page 177

e-mail chain with Jay Issa, who I'll let you know is an employee of 3M, Dr. Sessler, Mark Morken, another employee of 3M, Michelle Stevens, who is a medical director of 3M infectious disease, Jill Rector and Andrea Kurz. And I'm --
You know who Andrea Kurz is; correct?
A. Yes.
Q. Okay. If you look on the second page, it's an e-mail from Mark Morken to Dan, says, "Our group met yesterday to discuss the proposed retrospective review of SSI in Colorectal surgery protocol and we have the following questions or clarifications:"
And I want to go to number three. "The infection rate in the 1996 study went from 19 percent to 6.6 percent and in the background for this protocol the infection rate is 13 percent - why is there such a difference from what was achieved in 1996 and current status?"
And if you go -- look up, it's an e-mail from Dr. Dan Sessler to Mark. If you look at number three, it states, "Presumably the infection rates differ because the institutions and definitions differ. Importantly, about half the Clinic cases are inflammatory bowel disease, a group with a high infection rate, where most patients in the 1996 trial

have colon cancer. The treatment reported in 1996 is implausibly high (that is, the infection rate probably wasn't actually as low as in our 100 warmed patients). Knowing what we do know -- Knowing what we do now about fragile clinical trials, we would never have published such a small study."

Did I read that correctly?

A. You did.

Q. Okay. The fact that Dr. Sessler states that, knowing what he knows now about fragile clinical trials, he would have never published such a small study, which was the nineteen six -- 1996 Kurz study, does that change your opinion regarding the strength of the 1996 Kurz study?

A. Well it sound -- it sounds as though he is questioning the statistical pow -- power of the study's sample size. To the extent that that may, as his parenthetical comm -- comment suggests, alter the result with respect to the magnitude of the treatment effect, it is of -- of some import, but even -- even if the magnitude were substantially less but still substantial, I would say that I would still conclude from the study that warming is beneficial. And of course warming is beneficial not only for its impact on surgical-site infections but a variety of other

important outcomes.

Q. Okay. But you'd want to know what statistical reduction it is; correct?

A. Well my first -- first question is sort of "yes" or "no" is it beneficial. Beyond is it beneficial, "yes" -- "yes" or "no," how beneficial is it is of some interest. But with respect to making a judgment about the desirability of treating to prevent normothermia, the first question is by far the more important one, and it sounds as though -- I --

I don't see anything here that questions the direction of the treatment effect, --

Q. Okay.

A. -- only its magnitude.

Q. So the fact that most of the patients in 1996 had colon cancer doesn't affect, you know, the susceptibility of those patients with infection?

A. Well he -- he suggests, and I believe him, that the baseline infection rates differ according to the indication for the colon -- colon surgery.

Q. Were you ever showed document Exhibit 11 before today?

A. No.

Q. Okay. And you are aware that the patients were cooled in the Kurz study; correct?

A. You reminded me of that earlier.

Q. But were you aware of that before today?

A. When I originally read the paper, I'm sure I was.

Q. Okay. Well are you guessing, or were you sure that you --

A. Well if it was stated in the paper when I originally read it, I -- I'm sure I noticed -- noticed it.

Q. How were they cooled?

A. The paper has been published more than 20 year -- 20 years ago, so some of the details in fact have es -- have escaped me. But the impor -- the important point is some patients were warmed, some patients were cold. How they got -- got cold is, I think, the point you're address -- addressing. But there was a difference in their outcomes.

Q. Do you know how the patients were cooled in the Kurz --

A. I don't -- I don't recall. Probably a --

Well I don't want to guess.

Q. Okay. When was the last time you read the Kurz study?

A. Prob -- probably when I was constructing the performance measure.

Q. Okay. So it wasn't 20 years ago.

A. Wasn't 20 years ago, but it was more than a couple years ago.

Q. Well you didn't read it before you submitted your expert report, Exhibit No. 3?

A. I re -- I reviewed it. But the methodology by which the patients were -- were cooled is not an important consideration in judging the significance of the result. Warmer patients did better than cooler patients.

Q. Well to determine whether or not you need to have some sort of patient warming device, don't you think the information of what the control -- control group temperature is to determine whether or not the study is a valid study --

A. Well I'm not -- I'm not doubting whether patients, left unmanaged, become hypothermic. I think that's well established.

Q. Well even if they're managed they become hypothermic.

A. Some.

Q. But you agree with me that there's no scientific evidence to determine the level of hypothermic -- hypothermia and outcomes.

A. The res -- res -- results from Kurz and in

Page 182

fact others looked at patients above or below a bench -- a benchmark for hypothermia, typically 36 degrees or sometimes 35 and a half degrees.
Q. That wasn't my question, sir.
As we discussed earlier, there's no scientific study that indicates the -- the level of hypothermia and its effect on outcomes.
A. Well I'm not sure what you mean by "the level of hypothermia." If you're looking at the degree difference in temperature to the percentage of in -- of infection, that kind of relationship curve I don't think has been established.
Q. Okay.
A. But patients who are hypothermic, as defined by below -- depending on the study -- 36 or 35.5 degrees, are different from patients who are normothermic.
Q. Is that how you look at the Kurz study, is below 36 degrees? Did you not look at what the temperatures of the patients were, the control group?
A. Well the --
Q. "Yes" or "no," sir. Did you look at the temperature of the patients?
A. Yes. But I can't -- I don't recall what they --

Page 183

Q. They were 34.5 degrees.
A. Okay.
Q. Do you know what's significant about 34.5 degrees Celsius?
A. What's --
I'm not sure what you mean by that question.
Q. What happens to the body when you get below 34.5 degrees?
A. You try to compen -- compensate for the hypothermia.
Q. Yeah. You vasoconstrict; correct?
A. You vasoconstrict.
Q. Or vasoconstrict.
A. Vasoconstrict and -- and shiver, and there -- yeah, there are other mechanisms for compensation.
Q. Your body likes to hold 34.5 degrees Celsius on average.
A. I'm sorry?
Q. Your body does not like to get colder than 34.5 degrees.
A. Your body does not like to get colder than 35 degrees or 35.5 degrees.
Q. But your body has a reaction --
Are you aware of the studies, by the way, of

Page 184

what happens below 34.5 degrees Celsius?
A. What studies are you referring to?
Q. How the body -- how the body starts controlling the core temperature, and it's very difficult for the body to get below 34 --
A. Well if there are studies you're referring to, can I -- can you show them --
Q. You're the anesthesiologist.
A. Yes.
Q. Have you heard of those studies or not?
A. I'm aware of the body's physiological response to hypo -- hypothermia.
Q. Okay.
A. If there are specific studies you're looking for in that connection, you'll have to suggest --
Q. But you're aware there are studies out there that indicate that at 34.5 degrees on average the body vasoconstricts and holds -- holds the temperature as best as possible at 34.5.
A. No. It is not a -- not a switch that goes off -- off at 34.5. For some patients it will happ -- it will happen at a higher -- higher temperature. And it's a range.
Q. I said on average 34.5 degrees.
A. I don't know whether that is an av --

Page 185

whether that is an average, --
Q. Okay.
A. -- but when you're taking care of a patient in front of you, averages may not be that important. That is --
Q. Well let me ask you this.
A. Yeah.
Q. Why is hypothermia considered below 36 degrees?
A. It is be -- because things like surgical-site infections, cardiovascular morbid -- morbid -- morbidity, coagulapathy start to appear at -- at -- in that temperature range.
Q. Do you know what Dr. Sessler and Dr. Kurz say the reason why it's 36 degrees?
A. Why do they say?
Q. I'm asking you.
A. No, I don't know why they say.
Q. Do you think they know more than you?
A. Yes.
Q. Okay.
(Exhibit 12 was marked for identification.)
BY MR. ASSAAD:
Q. What's been marked as Exhibit 12 is an

Page 186

e-mail chain with Al Van Duren, Dr. Sessler, Dr. Kurz, and I will just say numerous employees of 3M at the time.

Have you seen this before, doctor?

A. No.

Q. Okay. I'd like you to turn to the bottom of page -- your first page. It's an e-mail from Dr. Sessler and it has Michelle Stevens, who is the medical director of 3M, as well as Al Van Duren, who is a -- has an upper-level position at 3M, as well as Gary Hansen. It says, "Hi Folks,

"One of the points Andrea and I tried to make at the KOL meeting in Washington" --

Do you know what "KOL" stands for?

A. I don't.

Q. Key opinion leaders.

A. Okay:

Q. -- "is that the evidence for hypothermia-related complications mostly does not meet current research guidelines for reliability and that previous studies were done with much larger temperature differences than are currently allowed."

Did I read that correctly?

A. Yes.

Q. Do you understand what Dr. Sessler is saying

Page 187

here?

A. I -- I -- I can in -- infer, but he's not -- he does not provide a lot of detail about what he means by "current research guidelines for reliability."

Q. Well you understand that we live in a world where published literature is peer-reviewed; correct?

A. Correct.

Q. And it's peer-reviewed for --

Reliability is one of the reasons why it's peer-reviewed; correct?

A. Correct.

Q. And if you have a methodology that's flawed, it might not be reliable and it might not stand up to peer review; correct?

A. Correct.

Q. Okay.

A. However --

Q. And reliability is --

I mean I understand you have a --

MS. LEWIS: He hasn't finished his answer.

MR. ASSAAD: He said "correct" so I moved on.

MS. LEWIS: He said "however."

A. Correct. However, if we are talking about

Page 188

the Kurz paper, not only was -- was it peer-reviewed, it was peer-reviewed by the most rigorous medical journal in the world.

Q. And even that medical journal, not -- things that are old in it are no longer reliable, correct, in the New England Journal of Medicine?

A. Well I would not agree with that blanket statement.

Q. Well science advances; doesn't it?

A. Correct. But red -- you know, hemoglobin still carries oxygen, so there are things that are old that are still reliable.

Q. Okay. And sometimes you look at things --

And right now I don't know if any doctor cools patients in the operating room during a surgery such as a colorectal surgery or total hip or total knee arthroplasty; is that correct?

A. That -- that is -- that is correct.

Q. Okay. Okay. So --

A. That is --

Whether that feature of the study design affects its reliability is something I am not able to judge.

Q. Okay.

A. I mean there may be ethical considerations

Page 189

about thinking about doing that -- doing that today, but whether that goes to the reliability of the stu -- of the study, the fact of the matter is that it is a -- it is an old -- old study and it is today probably still the most-frequently-cited piece of evidence on this subject, so the scientific community obviously understands its age but still regards what it contributes to our knowledge as substantial.

Q. Okay. Well you know that they're not just talking about the Kurz study here. Actually, he says, "One of the points Andrea" -- Ms. Andrea Kurz -- "and I tried to make at the KOL meeting in Washington" -- key opinion leaders -- "is that the evidence for hypothermia-related complications mostly does not meet current research guidelines for reliability and that previous studies were done with a much larger temperature difference than are currently allowed." Not talking about the Kurz study, talking about general evidence. Let's continue.

Did I read that correctly by the way?

A. You read that correctly.

Q. Okay. Let's continue. "Others have noted the same thing. See, for example, page 13 of the current issue of the ASA Newsletter which includes the following: 'The normothermia measure has the weakest

evidence supporting its ability to improve outcomes and is a complex, non-intuitive measure involving multiple inclusion of -- inclusion and exclusion criteria.'"

First of all, you were president of the ASA; correct?

A. I was.

Q. And what years were you president?

A. I was president in 2010.

Q. Until how long? It's one year?

A. It's a one-year term.

Q. Okay. So in two thousand twen --

You -- you -- you subscribe to the ASA Newsletter; correct?

A. I do.

Q. Okay. Do you recall reading an article on normothermia that said such a statement?

A. I don't recall --

Q. Okay.

A. -- this -- this quotation.

Q. Okay. Third paragraph, "The writing is on the wall. Without new evidence of harm from current levels of hypothermia, SCIP-10 is unlikely survive into the next version of pay-for-performance measures."

Did I read that correctly?

A. You did.

Q. Has SCIP-10 survived?

A. SCIP-10 has not sur -- survived, but I --

Q. So SCIP-10 has not survived; correct?

A. Has not survived.

Q. Okay.

A. Wait a minute. The reason it has not survived has, as far as I know, little to do with the underlying evidence base, it has to do with changes in -- in performance on that measure.

Q. Well you -- you weren't on the committee, were you, for SCIP-10, as we discussed earlier?

A. Correct.

Q. Okay. You're speculating at this point in time.

A. No. No. I am relating to you what I have read about the retirement of the SCIP infection control measure set, which was on the basis of the measures being -- they are called topped out.

Q. Simple question, "yes" or "no:" Has SCIP-10 survived since 2012?

A. No.

Q. Thank you.

(Exhibit 13 was marked for identification.)

BY MR. ASSAAD:

Q. Before we get to Exhibit 13, do you know what research the different type of surgeries that maintaining normothermia has been -- the research has been conducted on?

Do you understand my question?

A. Yes. So Kurz studied it in the context of colectomy pa -- patients; --

Q. Okay.

A. -- Melling studied it -- I think it was most -- mostly if not all breast -- breast surgery, --

Q. Breast and hernia.

A. -- breast and hern -- and hernia; Frisch studied it in hip-fracture surgery; and Scott studied it in a wide -- wide variety of surgeries.

Q. Okay. And Scott showed no difference in wound infections; correct?

A. No difference in wound infections. A dramatic reduction in infectious complications and other complications overall.

Q. But no difference in wound infections; correct?

A. Correct.

Q. Okay. And Frisch, I think it was total hip

and total knee, and it showed no difference in infection rates.

A. Well it depends which -- which -- which Frisch.

Q. Oh. There's more than one Frisch?

A. There's more than one Frisch.

Q. Okay. Which one did you consider, the one listed in Exhibit 2?

A. Yes.

Q. Okay. Exhibit 13 is a copy of a paper titled "Improving Perioperative Temperature Management;" correct?

A. Yes.

Q. And this was authored by you and Dr. Sessler; correct?

A. Correct.

Q. And we've discussed this previously; correct?

A. Yes.

Q. And even though it talks about the randomized outcome trials and benefits of normothermia, the -- the majority of this paper deals with quality-based payment systems; correct?

A. Yes.

Q. Okay. You do agree that practicing medicine

Page 194

is -- is that, it's practicing medicine; correct?
A. I have no idea what you mean by that.
Q. Well I mean things could change over time; correct?
A. Things change over time.
Q. Like you might think this antibiotic is good, but then you might say, no, it's actually not good, this antibiotic is better; correct?
A. Yes.
Q. You mentioned the laminar flow studies, and at one time they thought laminar was the greatest thing and now there's a question of whether it's good at all; correct?
A. Correct.
Q. Okay. So even though there are studies that talk about how great laminar flow is back in the '70s and '80s, now there's newer studies that question that; correct?
A. Correct.
Q. Okay. And you realize a lot of the studies that you cite with respect to maintaining normothermia are from the '90s.
A. Some of them are, yes.
Q. Most.
A. Well I -- I don't -- I don't know whether

Page 195

that's most of them, but yes, some of them are.
Q. I mean the Kurz study is '96; correct?
A. Yeah.
Q. Okay.
A. Frisch is 2016.
Q. And -- and Frisch shows no difference in infection rates.
A. Again -- again, that's the one that I asked to see the statistical workup on.
Q. I don't have it. But --
A. I'm sorry you don't.
Q. -- we agree that Scott, with respect to wound infection, which is the same type of study that Kurz and Melling were looking at, showed no difference in wound infections, and that was a 2015 study; correct?
A. Correct.
Q. Okay. When looking at the same thing --
A. If I may -- if I may --
Q. -- that Kurz and Melling were looking at, wound infections --
MS. LEWIS: You didn't let him finish his answer.
A. No. My point about Scott is that Scott looks at a whole variety of important clinical out --

Page 196

outcomes leading to patient morbidity and mortality beyond surgical wound infections, and the inescapable conclusion from looking at Scott is that -- is that managing patient temperature with forced-air warming benefits the patient.
Q. But you can't say that with re -- with respect to total hip and total knee arthroplasties because you don't know, the surgeries that occurred, which ones applied to orthopedic surgeries, correct, with Scott?
A. Scott does not iden -- identify which orthopedic procedures.
Q. But what we can say for sure in Scott is that with respect to wound infections in orthopedic procedures, there is no difference between SCIP compliant and SCIP non-compliant.
A. I don't think Scott broke out wound infections for separate analy -- for separate analysis.
Q. Okay. Are you familiar with the Clarissa Tjoakarfa study --
A. Does not sound familiar to me.
Q. -- entitled "Reflective Blankets Are as Effective as Forced Air Warmers in Maintaining Patient Normothermia During Hip and Knee Arthroplasty

Page 197

Surgery?"
A. No, I'm not familiar with that. No.
Q. Okay. Do you know why they are not --
Do you have an opinion whether or not reflective blankets are as efficacious as forced-air warmers in total hip and total knee arthroplasty surgeries?
A. Do I have an opinion?
Q. Yes.
A. Yes, I have an opinion about that.
Q. What's your opinion?
A. They are not as effective as active warming.
Q. What study have you performed to determine that?
A. You asked for my opinion, not for the result of a study.
Q. Well I'm hoping --
I don't want you to guess. Your opinion is based on some sort of fact or science. Do you have any fact or science to support your opinion that forced-air warming is more effective than reflective blankets?
A. No, I can't -- I can't --
Q. Okay.
A. -- point to that study.

Q. You're familiar with the studies comparing forced-air warming to the Hot Dog device; are you -- are you not?
A. I -- I have not -- I -- I have not studied -- studied them. My interest in this has not been so much about the comparative efficacy but the safety of the Bair Hugger, --
Q. Okay.
A. -- and so those are somewhat off point.
Q. Okay. Just so I understand, your opinion is that since there's no article that you agree with or you think is credible that the Bair Hugger is unsafe, that it must be safe.
A. That is in -- in part true, but it is also -- my opinion is also based on the fact that there is evidence that the risk of infections declines with the use of the Bair -- Bair Hugger, and that un -- unless I saw a clinical outcome study showing me -- showing me that the Bair Hugger was unsafe in that respect, I would continue to support its use and advocate for its safety.
Q. Can you --
And -- and try to get out for a second the -- the fact that you honestly believe that maintaining normothermia reduces the risk of

surgical-site infections. I don't want to talk about that any more. I want to talk about whether or not the Bair Hugger contaminates the sterile field or increases the bacterial load over the sterile field. Do you understand?
A. That's fine.
Q. Okay. Are you aware of any study that indicates that the Bair Hugger does not increase the bacterial load over the sterile field?
A. I am aware of --
So the bacterial load over the sterile -- sterile field, the particles, the bubbles and the air tur -- air turbulence are surrogates or -- or proxy -- or proxies for what I am interest -- interested in, which is the risk of harm to the patient, so the problem -- the problem is that that ev -- evidence is not addressing the key and important question here whereas the clinical studies do. In addition, most of the ones I have looked at, even as a non-expert on particle sci -- science, et cetera, have -- raise in my mind serious methodological flaws; namely, the experimental -- the experimental setup having nothing to do with the clinical setting in which we use the Bair Hugger.
MR. ASSAAD: Move to strike as

non-responsive.
Q. Listen to my question. Are you aware of any study that indicates that the Bair Hugger does not increase the bacterial load over the surgical site?
A. I -- I am not aware of it.
Q. Okay. Do you know what the Mistral warmer is?
A. I've heard -- I've heard of it.
Q. You know it's a forced-air warming device?
A. Yes, I know that.
Q. You know it's made by Stryker?
A. I didn't know that.
Q. Okay. Are you aware that Mistral, which is a forced-air warming device, warns the doctors regarding potential airborne contamination by its product?
MS. LEWIS: Objection, form.
MR. ASSAAD: Basis.
MS. LEWIS: It mischaracterizes the evidence, it's not a warning, and y'all have talked about that in other depositions.
MR. ASSAAD: Not a warning?
MS. LEWIS: No.
MR. ASSAAD: Okay.
A. I'm not aware of the non-warning.

Q. It is a warning. Your counsel is wrong. So --
A. I'm not --
I -- I -- I have a passing familiarity --
Q. Okay.
A. -- and recognition of the brand name and nothing -- know nothing more about Mistral.
Q. Are you aware that the older models of Bair Hugger --
Have you ever seen a model 200 series Bair Hugger?
A. I doubt -- I doubt it. I think the models I use are 500 series plus.
Q. And 700 series?
A. That I don't know about.
Q. Have you looked at the warning labels on the 200 series?
A. No, I don't think I've seen the 200.
Q. Has counsel showed you those labels -- I'm sorry.
Has counsel showed you those labels?
A. No, I don't believe so.
Q. Okay. Do you understand there was no verification testing on the Bair Hugger?
A. What does "verification testing" mean?

Q. I won't go into it because you don't know what it means.
Going back to your thousand hours sitting next to a Bair Hugger device, is it your testimony today that you've never felt heat sitting there as a sur -- as a -- as a doctor around the patient coming from the Bair Hugger device?
A. From the generator?
Q. From the blanket.
A. From the blanket. When I am in close proximity or my hands are underneath the blanket or I lift the head shield, yes, yes, I do, but when I'm sit -- sitting a foot and a half away from it, no, I don't.
Q. Would you be surprised if there were studies that indicated that the temperature around the surgical table and the surgeon increased significantly more with the Bair Hugger than with the Hot Dog device?
A. I -- I -- I wouldn't be -- I wouldn't be surprised, but I don't necessarily attach any significance to -- to that.
Q. Okay. Well if all of the air and heat are coming out at the neck, where do you think that heat's going to go?

A. It's mixing with the very substantially cool air in the room.
Q. You think it could change the temperature in the room by a few degrees?
A. No.
Q. Okay.
(Exhibit 14 was marked for identification.)
BY MR. ASSAAD:
Q. Exhibit 14 is a peer-reviewed article titled "Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients," and it's authored by Brandt, among others, including Oguz, Kurz and Kimberger.
Have you seen this article before?
A. No, I don't have.
Q. Okay. Under the conclusion it says, "Resistive-polymer warming performs as efficiently as forced-air warming in patients undergoing orthopedic surgery." Do you have any disa -- do you have any disagreement with that conclusion?
A. I have no basis to agree or disagree.
Q. Because whether or not you think maintaining normothermia is real science or junk science, it doesn't matter which way you warm, correct, as long as

you warm the patient?
A. As long as you warm the patient safe -- safely and effectively.
Q. I'd like you to turn to page 836, "Environment" -- I want you to look under Table 1, "Environmental temperature at 1 meter distance to warming device (after 30 minutes)," and do you see where it says 24.4 degrees plus or minus 5.2 degrees for Bair Hugger and 22.6 degrees plus or minus 1.9 degrees for Hot Dog?
A. Yeah.
Q. Huh?
A. Yes, I do.
Q. Okay. And you see that the OR temperature started at 19.5 degrees --
A. Uh-huh. Yeah.
Q. -- and it ended at 19.4? Do you see that?
A. Yeah.
Q. And around the warming device, at a one-meter distance around it, the temperature raised five degrees. Do you see that?
A. I -- I see that.
Q. And up -- and at some point up -- up over 10 degrees Celsius for the Bair Hugger based on the standard deviation.

Were you aware of this article, sir?
A. I said no.
Q. Has counsel -- has -- has counsel --
Would you be surprised if you were provided this article in the hundreds of articles that you received from --
A. It's poss -- it's possible it's --
Q. Okay.
A. -- it's -- it's in there.
Q. You just didn't review it before; correct?
A. As I said and you said your -- yourself, the point -- the point here is that we want to achieve normothermia safely, so my focus in reviewing the articles has been on the safety more than the efficacy.
Q. Would it be --
A. The other point -- the other point I make about this is that if -- if the Bair Hugger serves to warm the up -- rise -- raise the temperature around the patient, is that -- is that bad?
Q. Do you know if it's bad or not?
A. I don't think it's bad. I think we try very hard to warm the area around the patient. I think operating rooms are -- are too -- too cold.
Q. Do you know what the effect of heat is

around the operating room table on the sterility of the surgical site?
"Yes" or "no."
A. No.
Q. Okay. Move on then.
Do you think the data with respect to cardiac morbidity and thermoregulation is strong or weak?
A. It is strong.
Q. Have you done any research on it?
A. No, I haven't.
Q. Who has done research on it that you're aware of?
A. The original study we cited in the performance measure was -- was Frank, but I think that that was one of the endpoints also studied in -- in Scott. Wherever Scott is. Yeah.
Q. It's what?
A. It says Scott showed a reduction by 50 percent in the frequency of ischemic cardiovascular events, but the Frank, which is -- is also an older paper, also studied vascular patients and showed a lower frequency of morbid cardiovascular events in warmed patients.
Q. But you don't know what percentage of total

hip or total knee have actually car -- cardiac events.
A. No. No. As I said, I don't --
Q. Okay.
A. -- see that Scott has broken out those subpopulations.
Q. Do you recall what Dr. Kurz or Dr. Sessler said in their depositions regarding the effect of maintaining normothermia on cardiac events?
A. I --
No, I don't recall them specifically talking about them. And the statements we looked at a little earlier were very generic statements about -- about outcomes.
Q. Are you aware that 3M is conducting a large study in China now on that very issue?
A. No.
Q. Okay. And I take it you would defer to the researchers that have done the research on the relationship between normothermia and cardiac events with respect to their outcomes; correct?
A. Correct.
Q. I mean you're not basing any of your opinions on any of the work that you've done.
A. Correct.
MR. ASSAAD: Okay. Take a break.

THE REPORTER: Off the record, please.
(Recess taken.)
BY MR. ASSAAD:
Q. Ready to continue?
A. Yes, sir.
Q. So doctor, we talked about the Kurz study, the Melling study and the Scott study; correct?
A. We have.
Q. And the one study that we haven't talked about that you believe is authoritative is Frisch; correct?
A. I believe Frisch has influenced my opinion about the safety of the Bair Hugger --
Q. Okay.
A. -- and the -- and the efficacy of normothermia.
Q. All right.
(Exhibit 15 was marked for identification.)
BY MR. ASSAAD:
Q. Is Exhibit 15 the Frisch article you're referring to?
A. No, it's not.
Q. Okay. So you're looking at the one on hip fractures, not on hip and knee arthroplasty.

A. Correct.
Q. Would you agree with me that the one dealing with hip and knee arthoplasty are more relevant to this case than hip fractures?
A. Ever so slightly.
Q. What do you mean "ever so slightly?"
A. Because the nature of hip-fra -- hip-fracture surgery is very similar to hip arthro -- arthroplasty, so I think, even more so than the other studies, we're talking about the conclusions one would draw from that have special bearing on at least hip arthroplasty if not knee arthroplasty also.
Q. Well do hip fractures all have implants?
A. They have -- all have some kind of hard -- hardware.
Q. Okay.
A. Whether --
Some of them are repaired with a hemiarthroplasty, which, as its name implies, is very similar to a total hip arthroplasty.
Q. Okay. But you --
I mean this is the same Frisch though; correct?
A. I believe it is.
Q. Okay. Had you seen this article before?

Page 210

A. No, I don't believe I have.
Q. You have?
A. No, I don't believe so.
Q. You haven't. Okay.
I'd like you to go to page 60 of the article. And this was published in 2016. Are you aware of that?
A. It says 2017, but if you say it was published in 2016 --
Q. Oh, I'm sorry, you're right, 2017. It was -- it was submitted in 2016.
A. Okay.
Q. Do you see Table 3 where it indicates "Univariate Analysis of Complications Associated With Hypothermia?"
A. Yes, I do.
Q. And you see it says at the top TJA, and then halfway down -- a little more than halfway has TKA, do you see that?
A. Yes.
Q. And then if you go to the second -- other column it has THA on the right-hand side.
A. Yes.
Q. Okay. And also has p-values.
A. Yeah. So I infer from that that TJA is the

Page 211

combined results from TKA and THA. Is that what --
Q. Yes.
A. -- what they've done?
Q. Okay. And TJA stands for total joint arthroplasty. You agree?
A. Usually it does, yes.
Q. And TKA is total knee arthroplasty?
A. Yes, that's --
Q. And THA is total hip arthroplasty.
A. That's fine.
Q. And they talk about the normothermic and hypothermic patients, do you see that?
A. Yes.
Q. Okay. Do you see that every single comparison for MI, which is the mydocardial -- mydo -- myocardial infarction, --
A. Infarction yes.
Q. -- stroke, DVT, PE, DSSI, which is deep surgical-site infection, SSI, which is superficial surgical-site infection, and NSI, that there shows no statistically significant -- or difference that -- that is statistically significant among patients that are normothermic and hypothermic.
A. I see that.
Q. Okay. And that's for every single category

Page 212

there; correct?
A. Yes.
Q. Okay. And this is dealing with the same type of surgeries that are involved in this multi-district litigation.
A. Yes, it is.
Q. So based on this article and this raw data -- this data, you would agree with me that whether a patient is normothermic or hypothermic doesn't have an effect on total knee and total hip arthroplasties for an MI, a stroke, a DVT -- DVT, a PE, a DSSI, an SSI, an NSSI and an LOS, which is length of surgery.
A. I would agree that this study fails to demonstrate that difference.
Q. Or demonstrates that there is no difference.
A. Correct.
Q. Okay. And this is 2017; correct?
A. Correct.
Q. You were not provided this article by the defendant; were you?
A. I don't --
It does not look familiar to me.
Q. Okay. And this is one year --
This is an article that's dated one year

Page 213

after the Frisch article that you cited; correct?
A. The Frisch article I cited was 2016.
Q. Okay. And it's the same author.
A. I believe it is.
Q. Okay.
A. N.B. Frisch, yeah.
Q. I'd like you to go to Exhibit 7, which is the Sun study.
A. Sun, yes.
Q. This was Anesthesiology, a peer-reviewed ar -- journal. Are you familiar with Anesthesiology?
A. Yes, I am.
Q. Do you subscribe to it?
A. Yes, I do.
Q. Do you recall ever seeing this article?
A. No.
Q. Do you keep up to date with the literature in intraoperative core temperature management?
A. No more so than other clinical topics.
Q. No --
A. No more -- no more so to -- today than other clinical topics.
Q. Well do you focus on like maintaining normothermia and the literature out there on it?
A. Yes.

Q. And you've never seen this document before?
A. I missed this document.
Q. And this was on the -- I think --
I believe this was on the cover of Anesthesiology in February of 2015. You do not recall seeing it?
A. I don't recall seeing this.
Q. And you -- you left the practice of medicine earlier this year; correct?
A. Correct.
Q. Why did you leave?
A. Other demands on my time.
Q. Such as?
A. Such as -- such as foun -- foundation work and work for The Specialty Society and work at Harvard School of Public Health.
Q. Would you agree with me that prewarming has more of an effect on maintaining normothermia for the first hour of anesthesia time than does intraoperative warming?
A. I would -- I would agree with that.
Q. Turn to page 284. Have you seen Table 4 before or understand what -- what it's saying?
A. I have not seen Table 4 --
Q. Do you know what --

A. -- previously.
I'm sorry?
Q. Do you know what a degree-hour is? Have you heard that term in anesthesiology?
A. No, but I --
No, I haven't. Interesting. I have not -- I have not seen data on this subject presented in this way before.
Q. Have you e-mailed with Dr. Sessler in the past?
A. Yes, I'm sure I have.
Q. I assume those were on topics relating to normothermia?
A. In -- in -- indirectly. Our committee work, our author -- authorship, and our collaboration on presentation.
Q. You do understand that, based on this Sun article, it confirms the hypothesis that when a body goes under anesthesia, the -- the -- there's redistribution of heat to the extremities.
A. I believe that that's true. Whether this paper con -- confirms that or not I'm not able to say, not having seen it before.
Q. And that's why no matter what type of warming is used, you see a drop in temperature once

you start anesthesia.
A. Well I think we agreed a moment ago that prewarming by whatever mech -- mechanism would mitigate that to a degree.
Q. But you still see a drop.
A. You still see a drop.
Q. Okay. It's just a slower slope or lower slope than without prewarming.
A. Correct.
Q. Okay.
A. And I -- I believe that early application of active warming in the operating room probably changes that slope also.
Q. What other topics besides normothermia did you -- did you discuss with Dr. Sessler? What other type of work?
A. Well I just said -- I just said --
Q. Besides that.
A. None that I can think of.
Q. I mean do you --
Are you friends with Dr. Sessler, or was it mostly just a professional --
A. Mostly a professional relationship.
Q. Now you agree with me that, as we discussed, there could be a study to determine whether or not

Bair Hugger increases the risk of periprosthetic joint infections in total hip and total knee arthroplasty; correct?
A. There could be a study.
Q. There could be; correct?
A. There could be a study.
Q. Right. And are you aware that Dr. Sessler recommended on numerous occasions to 3M to perform such a study?
A. I'm not aware.
Q. Do you think a company has an obligation, if there is a -- someone such as Dr. Sessler that's requesting such a study who is a leader in -- in maintaining normothermia, that they should take that request seriously?
A. I -- I don't know what a large multinational corporation's obligations are.
Q. Do you think they have an obligation to the safety of the public?
A. To do -- to do studies as recommended by parties external to the corporation?
Q. No. To have a product that's safe for -- for the public.
A. Yes, I think they should have products that are -- that are safe.

Q. You drive a car; correct?
A. Yes.
Q. You -- you expect that the car manufacturer does what it can to ensure that the -- that the car is a safe car, especially if it gets in an accident; correct?
A. Yes.
Q. And you probably look into the safety of a vehicle in determining whether or not you want to buy the vehicle; correct?
A. Yes.
Q. And there's actually safety tests done on many vehicles, and you make a determination on -- for you yourself whether or not to purchase a certain vehicle or not; correct?
A. Right. And the analogy to what we're talking about is that I don't do the experiments on the safety of the cars myself, I rely on groups like the National Transportation Safety Board and oth -- and others, just as in this case I rely on groups like ECRI and the others I've mentioned previously to perform -- to perform that assessment.
Q. So your --
So my understanding is that you rely on third-party organizations to determine the safety of a

product and you don't rely on the manufacturer.
A. I rely on third parties evaluating the available science, coupled with my own clinical experience. And when I develop questions about safety, I will look at -- myself at individual studies as we've been discussing all -- all day. But as we have also noted, I don't do every experiment that pops -- pops into my head, nor do I expect the manufacturer to do the studies that I prescribe or recomm -- recommend.
Q. What studies did ECRI do?
A. ECRI --
Q. What studies did ECRI do --
A. ECRI --
Q. -- for Bair Hugger?
A. I'm not aware that ECRI did any studies for Bair Hugger.
Q. They relied on studies that -- some of which were funded by 3M or Arizant.
A. They may -- they may well have.
Q. Okay.
A. They did a systematic analysis of what has been published, and I have reason to believe that some of the published literature has been funded by 3M, some has been funded by Hot Dog -- Hot Dog, and I'm

sure numerous other sources.
Q. Okay. So the ones funded by 3M you give credibility to, the ones that were funded by Hot Dog you don't give credibility to.
A. No, I didn't say that at -- at all.
Q. Okay.
A. That's a pretty bald misrepresentation of what I've been saying.
Q. But with respect to, for example, your -- your car, do you -- do you think the manufacturer has a duty to perform studies to determine whether or not the car is safe?
A. I -- I think the man -- manufact -- I think the manufact -- manufacturer has to supply information. Whether they do studies or not, I'm not sure. But I think all of us rely on an impartial source that is going to reliably be objective, and that's why I look at NICE and ECRI and others, and that's why you look at the National Transportation Safety Board and similar groups and you and I -- you and I don't necessarily take Chevrolet's claim that they make the safest car around at face value.
Q. You rely on the manufacturers of all the products you buy that you use, that they have done their due diligence to make sure that the product is

safe, or at least to warn you about it if it's not.
A. Yes.
Q. Okay. There's a duty among a manufacturer to provide safe products, and if there's a risk, to warn you of the risk. Do you understand that?
MS. LEWIS: Objection to the form of the question.
A. Well --
Yes.
Q. Like, for example, a typical iron usually has that little sticker on it that says keep out of water, you know, when it's plugged in because it could cause an electrocution. You -- you know what I'm talking about; right?
A. Yeah.
Q. Okay. Now they make the iron safe and it's not going to explode, but they warn you of the risk of getting it wet when it's plugged in; correct?
A. Correct.
Q. Okay.
A. So they warn you about the risk of getting -- of getting it wet. I don't think they warn you about the risk of dropping it on your -- on your head. So I think that what we expect are warnings that are pertinent to reasonably corr -- correct and

appropriate use of the device.
Q. And the appropriate use of a device is using the device as it was intended to; correct?
A. Yes.
Q. And even when you use devices the way they are intended to be used, there still exists warnings for certain devices; correct?
A. Right.
Q. Okay.
A. Those are the ones --
Those are the warnings that I think are pertinent.
Q. Okay. Now you are familiar with the 700 series Bair Hugger; correct?
A. I believe my experience has been with 500 -- the 505 and 5 -- 575. I'm not sure whether we had the other model -- the other model in clinical use.
Q. Is the one you use white or blue?
A. They're -- they're white.
Q. Okay. So you've never used a 750.
A. Probably not in -- not in the operating room. I think they may be 750s in recovery.
Q. When's the last time you used the 505?
A. Probably the last week in December of 2016.
Q. Do you know the 505 has been discontinued

for a year?
A. I -- I didn't -- I didn't know that. I know we have newer ones.
Q. Which are blue?
A. No. We have white -- all --
In the operating room we have all white Bair Huggers.
Q. Okay. So you've never seen a 750.
A. Well is the 7 --
The 750 is a blue model Bair Hugger?
Q. Yes.
A. I probably have seen it, but I don't think we have them in the operating rooms. They would be in other -- other areas.
Q. What about Bair Paws, have you seen Bair Paws?
A. Only advertising for Bair -- Bair Paws.
Q. You don't think prewarming is important?
A. I think prewarming is valuable.
Q. Do you have prewarming in your hospital?
A. No.
Q. If it's valuable because of the patient, why don't you do it?
A. Because there are logistical barr -- barriers to -- to doing it.

Q. What's the logistical barrier?
A. The patient -- patients in the -- are in the pre-op area for a brief period of time, they're in -- being moved from -- from place to place, and places that have done it have anecdotally report -- reported that people in the vicinity are uncomfortable with the heat.
Q. When you say "people in the vicinity," you're talking about hospital staff?
A. It's usually mostly fam -- family mem -- members who are sitting by the patient's side.
Q. What about using VitaHEAT?
A. I don't know about VitaHEAT.
Q. It's actually battery powered. You could actually stick it in the mattress and roll it wherever it goes.
A. Okay. Looks like you could be a salesman for VitaHEAT.
Q. Well I'm wondering if pre-op -- prewarming is so important, so beneficial, how come someone such as yourself that looks for pay-for-performance measures hasn't investigated the options you could use for prewarming.
A. Well my experience with intraoperative warming is that the frequency of reaching target

temperature is extraordinarily high, so that I am achieving what I want to achieve -- achieve without pre -- prewarming.
Q. Your patients are different than everyone else's patients around the world?
A. I don't know what you mean by that.
Q. Well everyone becomes hypothermic. There's a huge --
I mean the Sun article says that even in intraoperative warming, that most patients become hypothermic in the first hour.
A. I'm not talk --
I'm talking about -- talking about reaching a target -- a target temperature by the end of -- by the end of surgery or on arrival in the recovery room, which is what the measure prescribes.
Q. Okay. So do you know whether or not becoming hypothermic during the intraoperative period increases the risk of infection, or is it becoming hypothermic while you're in the PACU increases the risk of surgical-site infection?
MS. LEWIS: Object to the form.
A. Right. So I think that becoming hypothermic at the time at -- at which you are wanting your physiologic defenses to be optimal is -- is

deleterious. You are corr -- correct that most patients become hypo -- hypothermic. If you are warming them, they are transiently so, and they reach target temperature, you know, within -- within an hour, if that -- if that, of applying the forced-air warming.

Q. All right. Okay. Is it your opinion that if a patient develops a periprosthetic joint infection 30 days out of -- from the date of the operation, that if he was hypothermic during the in -- during the procedure, that could be a significant -- or be a risk factor for him developing a PJI?

A. Well I think hypo -- hypothermia is a risk factor for developing P -- PJI. Admittedly, as we've discussed repeat -- repeatedly based on ex -- physiology and extrapolation from other -- other settings, if there is a critical moment at which the temperature matt -- matters, I'm unable -- unable to say.

Q. Go to your report, Exhibit 3. On page two, top paragraph, you write, "The use of forced air warming has provided patient comfort and reduced postoperative shivering, a side effect that is very unpleasant for patients..."

Did I read that correctly?

A. Yes.

Q. Which is a more unpleasant side effect, a periprosthetic joint infection or shivering?

A. A periprosthetic joint infection.

Q. Okay. And you go on, "...in addition to reducing the risk of cardiovascular and bleeding complications."

Did I read that correctly?

A. Yes.

Q. But you have no evidence sitting here today that there is a reduction in cardiovascular risk with patients that undergo total hip or total knee arthroplasty; correct?

A. I have no reason to believe that the risk of those complications would be substantially different in joint arthroplasty patients from others.

Q. I understand you can believe in anything you want, sir. My question is: You have no evidence to support that belief; correct?

A. I have no evidence to support what -- what -- what belief?

Q. That there's -- that there is a -- there --

That hypothermia increases the risk of cardiovascular in total hip and total knee arthroplasty surgeries.

A. I -- I have ev -- evidence. If what you're looking for is a specific study addressing those complications in total joint arthroplasty patients, I would say no, --

Q. Okay.

A. -- but the evidence qualifies in my mind to a level substantiating that clinical practice.

Q. Are you aware that Andrea Kurz informed 3M that her 1996 study only applied to colorectal surgeries and not to extrapolate into other surgeries?

A. I'm not --

Q. Are you aware of that?

A. I am not aware of what she has said to 3M.

Q. Okay. You agree with me that a colorectal surgery is way different than a total knee arthroplasty.

A. It is different, it is different, but it has many characteristics in common with other kinds of surgery.

Q. Let me guess. They use a scalpel, correct, in both?

Let's talk about the length of surgery. Is the length different between the two surgeries?

A. Marginally, perhaps.

Q. Marginally?

A. Yes.

Q. Did you look at the length of time for surgery for the 1996 colorectal study?

They were two to four hours. Are you aware of that?

A. And so what -- what were --

What was the length of total joint arthroplasty --

Q. On average an hour.

A. -- at that time --

Q. On average an hour.

A. -- in 1996?

Q. Well we're talking about 2017 today; aren't we?

A. Right. So what's the length of colon -- colon surgery in 2017?

Q. I don't know what it is.

A. It's apples, and let's talk apples and apples.

Q. Okay. You want to talk apples and apples, sir? Let's talk apples and apples. You want to apply a 1996 study, which is oranges, to a -- to a 2017 colorectal surgery, which is apples? You want -- you want to just use data that supports you that's apples and oranges right now, but when -- when it goes

against, you can't compare?
A. No. But the --
MS. LEWIS: Objection, argumentative.
A. -- the -- the physi -- the physiology, number one, has not changed since 1996, and the physiology of the microcirculation and host defenses is not substantially different from one operation to the -- to the other.
Q. One's a clean surgery, correct, the total knee?
A. Correct.
Q. And colorectal is a dirty surgery; correct?
A. Correct.
Q. There's more heat lost when you open up the abdomen than when you open up the knee; correct?
If you know. Or if you don't know, you can say you don't know.
A. I would agree with that.
Q. Okay. There's way more bacteria in a colorectal surgery around the surgical site because of what you're cutting into than within knee surgery; correct?
A. Correct.
Q. Okay. So they're not apples to apples; are they, doctor? Two different surgeries.

A. They are --
I concede that they are two different sur -- surgeries.
Q. Okay.
A. There are differences.
Q. Okay. So how -- so you can't --
You know, let's talk about open-heart surgery. Okay. That's different than a total knee surgery; correct?
A. Correct.
Q. The -- the -- the risk of a cardiovascular event in an open-heart surgery is much greater than it is in a knee surgery; correct?
A. Correct.
Q. Okay. Surgeries --
There's different surgeries. You can't com -- you -- you can't make all the surgeries the same to support your opinions that maintaining normothermia is -- is effective for every type of surgery. You have to look at case by case; don't we, doctor?
A. It would be nice to be able to do so.
Q. Okay.
A. But the evidence of benefit in cases other than joint arthroplasty is persuasive, and in the

absence of any credible evidence of a reason not to apply it more broadly, I believe it is sound practice.
Q. That's not evidence-based medicine; is it?
A. We don't have evidence for every clinical decision we make.
Q. Okay. I get that. So there's no evidence that maintaining normothermia reduces the risk of cardiovascular events in total hip or total knee arthroplasty.
A. There is no specific study in that patient population. I am drawing distinction between that and evidence in the sense that I look for evidence in making deci -- in making decisions.
Q. Doctor, do you even know what the risk of cardiovascular injury is in a total hip or total knee arthroplasty?
A. I don't know what that statistic is.
Q. It might be zero for all we know.
A. No, it's --
I'm sure it's not zero.
Q. It's probably --
It could be a super, super low number.
A. If you want to speculate that that's the case, given the fact that these are often elderly patients with comorbidities, I would question it, but

I think neither you or I have the statistic to --
Q. I'm not an expert here, doctor. You're the -- you're the doctor.
A. Okay.
Q. You're the one that's saying that maintaining normothermia reduces the risk of cardiovascular injury in a total hip and total knee arthroplasty; correct?
A. Correct.
Q. But you don't know what the risk is with or without maintaining normothermia for a cardiovascular injury in a total hip or total knee arthroplasty; do you?
A. I just saw that the risk of morbid cardiovascular events in a broad range of surgeries was reduced about 50 -- about 50 percent. I think it is completely fair and legitimate to apply a finding like that to total joint arthroplasty patients. And similarly, the original Frank paper, which dealt with vascular surgery patients with a high incidence, if you can favorably impact the risk of cardiovascular events in a high-risk population like -- like that, you ought to be able to have an impact on -- on lower-risk patients.
Q. Do you know what a heater-cooler unit is?

Page 234

A. I know what a heater-cooler is, yes.
Q. Is it used in arth -- in a arth -- arthroplasty surgery?
A. No.
Q. Why not?
A. Because you're not making the patient hypothermic and rewarming them.
Q. I mean there's no benefit for -- for making --
A. It has no application. It has no relevance.
Q. Okay. So before you --
You agree that before you use a device, you should determine whether or not it has a benefit to the patient; correct?
A. Yes.
Q. And there's different types of surgeries. There is open-heart surgery; correct?
A. Yes.
Q. There's abdominal surgery; correct?
A. Yes, there is abdominal surgery.
Q. There's brain surgery; correct?
A. Yes.
Q. For example, you don't want to cool a patient in -- in arthroplasty because it has no benefit; correct?

Page 235

A. Correct.
Q. Okay. And I'm asking for what are the benefits of warming a patient during arthroplasty, not colorectal. Talking about arthroplasty surgery. And that's something you should know before you make the patient pay money for a device that they may or may not need; don't you agree?
A. I should make a -- make my best judgment about whether it's beneficial.
Q. Okay. The only thing that we know today, okay, is that forced-air warming is potentially beneficial for colorectal surgeries according to a '99 -- 1996 Kurz study with respect to intraoperative warming.
A. I -- I don't -- I don't believe that's -- that we just -- we -- we just --
Q. That's all you have, doctor.
MS. LEWIS: Can you let him finish his answer, Gabe?
A. We just -- we just looked at a paper which showed reduced -- reduced blood -- blood loss in -- in those patients.
Q. Really? You want to talk about the Sun article?
A. Is that what it is?

Page 236

Q. Let's talk about the Sun article, sir. Do you want time to read the article before you make that statement?
A. Sure.
Q. Okay. Why don't --
Let's take a break and you can read it, and I'd -- I'd tell you to focus on degree-hours, focus on degree-hours before you're going to make that statement with respect to arthroplasty surgeries.
MR. ASSAAD: Let's take a break.
THE REPORTER: Off the record, please.
(Recess taken.)
BY MR. ASSAAD:
Q. Doctor, did you have time to read the Sun article?
A. Yes, I did.
Q. Okay. Turn to degree-hours on Table 4.
Do you understand what an odds ratio is?
A. Yes.
Q. Okay. And do you understand when it says "Area under 37 degrees Celsius (degree-hours)?"
A. No.
Q. Okay. So you don't understand what the authors here are indicating with respect to blood loss and degree-hours.

Page 237

A. Well from the -- from the text I gather that they are looking at the dura -- duration of hypothermia.
Q. Below 37 degrees; correct?
A. Corr -- correct.
Q. And for how long as it is; correct?
A. Yes.
Q. Okay. So you agree with me that the adjusted odds ratio for a patient that is 35 degrees Celsius for two hours would be about 1.06.
A. I don't see -- I don't see where you're getting -- getting that.
Q. Okay. So I -- I don't want you to guess, so if you don't understand the chart, then we don't have to go through the chart. Is that fair?
A. Well the -- the discussion of the statistical methodology, which I think produced the charts in this -- in this paper, is beyond my expertise.
Q. Okay. You'd defer to someone like Andrea Kurz who is an author on -- on this paper.
A. Well in this case I def -- I defer to the editor of the journal who says, "Hypothermia significantly increased -- significantly increased both transfusion requirements and duration of

Page 238

hospitalization..."
Q. The editor or the author?
A. The editor.
Q. Where are you referring to the editor?
A. "What This Article Tells Us That Is New."
Q. Okay. How would you apply this to total hip and total knee, if you know?
A. Well, it is another ar -- argument for the benefit of minimizing hypothermia.
Q. Okay. So if a total knee or total hip usually lasts about an hour to an hour and a half and --
A. An hour to two.
Q. -- an hour to two, and the temp -- and the patient -- let's --
Let's look at this real quick. Go to page 282. You agree with me that only 2.1 percent of patients below 35 degrees Celsius were operations on the musculoskeletal system?
A. Yes. And -- but I'm not clear whether this refers to at any -- at any moment or at the end of -- or the end -- end-of-case temperature, --
Q. Okay.
A. -- which is shown separately. So I don't know what that means.

Page 239

Q. Okay. Well we'll just agree that the document speaks for itself; correct?
A. The document speaks for itself.
Q. Okay. If we also look at the Frisch article, which is Exhibit 15, let's go to page 59 and let's look under total -- total knee arthroplasty.
A. Yeah.
Q. If you look at -- on -- on Table 2 on the right-hand side, which is total knee arthroplasty, it says EBL. What does EBL stand for?
A. Estimated blood loss.
Q. And you agree there's no statistically significant difference between the patients that are normothermic and the patients that are hypothermic; correct?
A. Correct.
Q. And if you look below that under total hip arthroplasty and you look at the estimated blood loss, again there's no statistical significance between the es -- estimated blood loss between patients that are normothermic and the patients that are hypothermic; correct?
A. Correct.
Although I'm looking now at the authors' abstract, "...hypothermia was associated with

Page 240

increased estimated blood loss..." So let's -- let's -- let's find that.
Q. If you look under total -- total joint where he combines the two, you'll see a difference.
A. Okay.
Q. But you agree with me that the knee is a different location than the hip; correct?
A. The knee is a different location of the -- of the -- of hip. Because it's, you know --
Q. So when you compare apples to apples and oranges to oranges, you don't see a statistically significant difference between --
A. Yeah. It raises all kinds of questions in my mind how you could take a cohort of patients in which you have no difference, combine it with another such cohort, and come up with a highly significant diff -- difference.
Q. But you don't know the answer to that sitting here today.
A. Correct.
Q. Okay.
A. But that is --
But the conclusion that the authors draw is that hypothermia was associated with increased blood loss.

Page 241

Q. What percentage of hospitals in the United States have laminar airflow?
A. I don't know.
Q. Does your OR have laminar airflow?
A. We have -- we have two rooms with laminar airflow.
Q. Is it laminar or unidirectional?
A. It's been described to me as laminar. Whether that is technically used correctly when it's been described to me, I can't necessarily say.
Q. Okay. Do you know whether or not a laminar airflow OR even exists?
A. So I -- so I have heard.
Q. Do you know what "laminar" means?
A. It means -- it means uni -- unidirection -- unidirectional.
Q. You're not an engineer; correct?
A. I'm not an engineer.
Q. Okay. Do you --
You understand "laminar" is an engineering term?
A. Yes.
Q. Okay. And "turbulent" is an engineering term?
A. Correct.

Q. You say the Bair Hugger is located outside the laminar flow area.
A. Yes. It should be, proper use.
Q. What's outside the laminar flow area?
A. So the laminar flow area is mar -- is marked sometimes on the floor of the operating room but almost always by a plexiglas curtain over -- overhead. The air outside that ar -- area is not -- is not laminar flow.
Q. And you're talking about the Bair Hugger blower; correct?
A. Well I'm talking about the Bair Hugger blower for certain in most instance -- instances, particularly with total joint arthroplasty. The Bair Hugger blanket is usually located outside the curtain as well.
Q. Okay. And by the way, you have issues with laminar flow; correct?
A. I don't have issues with lam -- lam -- lamin -- laminar -- laminar flow, but I am aware that, as you described earlier, that the enthusiasm about its benefit in years past has waned with contradictory evidence. So I would -- I would say that it is an unsettled matter, at best, whether it is beneficial for surgical patients.

Q. Have you raised that issue with the people at the hospital?
A. If I recall, 20 years ago when this facility was built there was a bit of a debate about whether to invest in it or not -- or not. I was not a primary decision-maker on that.
Q. But recently and in preparing your report and raising that issue, which you also raised in the Walton case, have you raised that issue with -- with people at the hospital that you were employed at?
A. No.
Q. Okay.
A. I mean if we were building a new facility to -- today, I would probably be part of the conver -- conversation, but I think the engineers and orthopedic surgeons would be the ones who were most persuasive in driving the decision.
Q. And you would defer to the engineers with respect to airflow in the operating room.
A. Correct.
Q. Okay. You write on page four, "Based on a frequently cited study, the air emitted from the Bair Hugger blanket does not produce bacterial growth when cultured."
A. Yes.

Q. And you cite Avidan for that; correct?
A. Yes.
Q. Do you believe Avidan is a good study?
A. Yes.
Q. Okay. You don't think it's underpowered in any way?
A. No.
Q. Okay. How many times did they test to see whether or not they could culture bacteria from the Bair Hugger blanket?
A. I think there were nine -- nine -- nine samples or nine trial runs.
Q. In Avidan from the Bair --
A. I think -- I think that's right. Yes.
Q. From the Bair Hugger blanket.
A. Yeah. I'd be happy to take a look at the -- at the paper to refresh my mem -- memory, but I think that's --
Q. Okay.
A. -- that's my recollection.
Q. Okay. So your recollection is they tried nine times -- or eight or 10 times, whatever, give or take -- and -- from the Bair Hugger blanket to culture bacteria.
A. Correct.

Q. Okay.
A. And it said nine trials, each of -- each of which had an array of culture -- culture media. And again, my recollection is that in the nine trials, none of the arrays of culture media grew any bacteria.
MR. ASSAAD: Move to strike as non-responsive to a non-existent question.
Q. You next talk about the body heat emanating from the surgical staff. Do you know how many BTUs per hour the Bair Hugger produces?
A. No.
Q. Do you know how many BTU -- BTUs per hour a -- a person produces?
A. No, I don't.
Q. Okay. Do you know --
I mean you're not an expert in heat transfer; correct?
A. Correct.
Q. You're not an expert in fluid dynamics; correct?
A. Correct.
Q. So you have no opinion with respect to how the Bair Hugger blanket may affect the OR environment by the heat it produces or the airflow it produces.
A. Correct.

Page 246

The commentary here is questioning the studies that claim to describe how the Bair Hugger influences those factors.
Q. Excuse me. I didn't understand you.
A. The commentary in this letter are meant to address the shortcomings in the studies that purport to address the disruption in laminar flow and related -- related factors; that is, as we've discussed previous -- previously, the -- the experimental mod -- model either having no per -- personnel, mannequins, no instruments, no Bo -- no Bovies, et cetera, so in looking at -- at those, my conclusion was they -- for me, not being a particle or airflow expert -- they still lacked face validity on that basis.
Q. Well hypothetically speaking, if by adding individuals would make the effect of the Bair Hugger worse, would that affect your opinions regarding those studies?
A. Regarding these studies. But what I would say is that the studies of particle counts and air -- airflow patt -- patterns, their relevance to the risk of infection is un -- is -- is unproven, so that even if the particle counts --
Q. I'm not talking about infection, I'm talking

Page 247

about particle counts and bubbles.
A. Well --
Q. Okay? If --
A. And I'm -- I'm going to -- I'm going to say -- say that from my point -- point of view, particle counts and bubbles are poor proxies or surrogates.
Q. And what's your basis?
A. Because I have not seen any evidence connecting them with the risk of infection.
Q. Have you not looked at the Darouiche study?
A. Show me the Darouiche study.
Q. Have you looked at it? "Yes" or "no."
A. That doesn't sound familiar.
Q. Okay. Defense are very -- all aware of the Darouiche study and the Stocks study. Have they not shown that to you?
A. Stocks --
MS. LEWIS: Objection to the form of the question.
A. Stocks sounds familiar. Rouiche -- Rouiche -- Rouiche does not.
Q. Do you know who Rabih -- do you know who Rabih Darouiche is?
A. No.

Page 248

Q. So you're not aware of his study that -- that correlated bacterial load over the surgical site with periprosthetic joint infections.
A. No.
Q. And in fact not --
He even went further and said the bacterial load had an effect on periprosthetic joint infections but not superficial wound infections. Are you aware of that study?
MS. LEWIS: Objection to the form.
A. Are you talking about the same study?
Q. Yeah.
A. Same study? No, I'm still not aware of.
Q. Would that affect your opinions if those statements are true?
A. The --
MS. LEWIS: Objection to the form of the question.
A. Yeah. Repeat the question.
Q. Darouiche --
In the Darouiche study, he correlated bacterial load with periprosthetic joint infections and also showed there was no relation between bacterial load over the surgical site and superficial wound infection. If -- if that study is accurate,

Page 249

would that change your opinion with respect to bacterial load causing periprosthetic joint infection?
MS. LEWIS: Object to the form.
A. It -- it might, but I would not make any conclusion about that without the opportunity to review it in -- in detail --
Q. Okay.
A. -- and presuming that the details of the study -- study were i -- i -- items with which I could intelligently, based on my background and experience, assess.
Q. Let me ask you this, doctor: Hypothetically speaking, if the Bair Hugger increased particles over the surgical site, and assuming that the increased particles over the sur -- over the surgical site indicated increased bacterial load over the surgical site, and there was also a study that indicated increased bacterial load over the surgical site increases the risk of total hip and total arthroplasty periprosthetic joint infections, would that change your opinion with respect to whether or not the Bair Hugger significantly increases the risk of periprosthetic joint infections in total hip or total knee arthroplasty --
MS. LEWIS: Objection --

Q. -- if all the statements are true?
MS. LEWIS: Objection to form.
A. Perhaps, but not to the extent that a clinical outcome study, Bair Hugger/no Bair -- Bair Hugger, would -- would have.
Q. Who do you think would fund a study with respect to the clinical outcomes on total hip and total knee arthroplasty periprosthetic joint infections with the use of the Bair Hugger or the use of a different warming device?
A. I'm not able to speculate on who might fund that.
Q. Do you know how much that study would cost?
A. I don't know.
Q. Would you be surprised it would be millions of dollars?
A. Would I be -- would I be surprised? No, I wouldn't be surprised.
Q. I mean just say assuming that the periprosthetic joint infection rate for total hip and total knee is two percent, do you know how many patients you would need to conduct a study to show a difference in an infection rate that's only two percent?
A. No, I don't know the number.

Q. Okay. More than 10; right?
A. Yeah. Presumably, yes.
Q. Probably more than a thousand.
A. I -- I -- I don't know.
Q. With respect to McGovern, you criticize McGovern because of the change in infection prevention practices during the study period; correct?
A. Among other things, yes.
Q. Well that's what you put here. Oh, motionless. But with regard --
With respect to the clinical data, it's the change in infection prevention practices; correct?
A. And the anticoagulation practices.
Q. Well that's not in here; is it?
A. No, but it's true.
Q. Well I'm looking at your report. It's not in your report; correct?
A. Yes, that's true.
Q. Okay. So let's just talk about the infection prevention practices. Are you talking about the prophylactic antibiotics?
A. Yes.
Q. Do you know whether or not the change in the pro -- that the prophylactic antibiotics -- strike that.

Are you aware of any study that compares the two anti -- different antibiotics that were used to determine whether or not any one of them had a -- a better or worse effect on periprosthetic joint infections?
A. I -- I -- I don't know.
Q. Okay. If there was a study that indicated that the prophylactic antibiotics were -- they -- they were not inferior to each other, would that affect your opinion of whether or not the change in antibiotics had an effect on the results?
A. I -- I -- I think the results of this -- this study should control -- controlled for that.
Q. Well why don't you answer my question.
A. If there were effectively no change in the anti -- antibiotic --
Q. That wasn't my question, sir. Why don't you listen to my question. We'll -- we could get out of here really soon. If there is --
If there was a study that indicated that the two antibiotic -- the two different antibiotic regimens used in the McGovern study were non-inferior to each other, means there was no difference, would that affect your opinion of whether or not the change in the prophylactic antibiotics used had an effect on

the McGovern results?
MS. LEWIS: Object to the form.
A. I would be -- I would be less -- less concerned --
Q. Okay.
A. -- but not unconcerned.
Q. Okay. You say that more than 5,000 public and private institutions rely on ECRI. Is that correct?
A. Yes.
Q. What's your basis?
A. ECRI.
Q. So you rely on ECRI to tell you who relies on ECRI?
A. ECRI -- yeah. I think that came from ECRI's annual -- annual report.
Q. Well there's a difference of public and private institutions relying on ECRI or them -- or people subscribing to the ECRI website. Do you understand the difference?
A. Okay. Okay.
Q. I mean you subscribe to the Anesthesiology Journal; correct?
A. Yes.
Q. You don't rely on every article that's

Page 254

published in the Anesthesiology Journal; correct?
A. But to a degree I rely on it; otherwise, why would I subscribe to it?
Q. Because there might be some good parts, there might be some bad parts; correct?
A. Correct.
Q. I mean there's some articles that I assume an independent doctor would read and be like I just disagree with -- with the research or disagree with the conclusion; correct?
A. Yes.
Q. Even though you subscribe to Anesthesiology; correct?
A. Yes.
Q. So you really can't sit here and say that more than 5,000 public and private institutions rely on ECRI for evidence, reports and assessments of healthcare technology, but what you can say is there's probably 5,000 people that subscribe to it. Fair?
A. Yeah. I'm not sure that it's people as much as institutions.
Q. Okay. You don't know whether or not the institutions are relying on the data that ECRI provides; correct?
A. I don't -- I don't know the extent to which

Page 255

they do so.
Q. That would be pure speculation; correct?
A. Correct.
Q. Okay. Now you'll agree, with respect to the heater-cooler devices, that the bacteria was aerosolized on water vapor and traveled to the patients; correct?
A. That is -- that is what was reported.
Q. Okay. And you have no reason to disagree with that; correct?
A. I have no reason to disagree.
Q. It wasn't by direct contamination but by indirect contamination.
A. I'm not sure what you mean by "direct contamination" or "indirect contamination."
Q. You don't know the difference?
A. I don't know what you mean.
Q. Okay. When you say it's been aero -- aerosolized, it traveled through the air; correct?
A. In -- in -- in liquid.
Q. Okay.
A. In water.
Q. In water vapor.
A. In water vapor.
Q. Okay. Do you know how small a water vapor

Page 256

is?
A. I don't know.
Q. Do you know whether water vapor is equivalent in travel -- in the way it travels in the air to neutrally buoyant bubbles?
A. I don't know.
Q. Do you know whether or not it is similar to the way it travels with squames?
A. I don't know.
Q. Okay. But we do know that water vapor could travel from where the heater-cooler is and -- and blown by the fan of the heater-cooler to the surgical site; correct?
A. That is what the alert implied.
Q. Okay. And you're aware that the heater-cooler unit is much further away from the sterile field than the Bair Hugger is.
A. I don't know that.
Q. Okay. You've never used a heater-cooler unit?
A. Well I've been many -- many years ago in a cardiac opera -- operating room, but it depends where the pump -- where the pump and the heater-cooler sit.
Q. And you're not disputing that an implant can be contaminated by airborne contamination; are you?

Page 257

A. I think it is -- I think it is possible. I think contamination of sur -- of surgical wounds is principally from the skin and subcutaneous flora of the patient.
Q. Except when the heater-cooler is involved, then it can be contaminated by the heater-cooler.
A. I --
Again, I think that's the implication of the FDA alert.
Q. I mean you're citing it. Do you agree with it or not?
A. Yes.
Q. Okay.
A. Yeah.
Q. So -- so a wound could be contaminated by airborne contamination.
A. Right.
Q. Okay.
A. A -- a wound -- a wound can.
Q. Okay. I mean that's why you have unidirectional flow or laminar flow and filters and HVAC systems, to provide the cleanest air possible at the OR; correct?
A. Yes.
Q. I mean that's why you have positive pressure

Page 258

in the OR; correct?
A. Yes. Yes.
Q. To keep contaminants out.
A. To keep contaminants out. What the relative risk of those contaminants are in surgical in -- infections is less clear. As I said, the -- what I have been taught is that it is about the skin -- skin and subcutaneous flora as the source of surgical contamination. And while it may be possible that the air is a contributor, I am unable to describe its relative contribution and therefore risk.
Q. But you're basing this on what you were taught 25 years ago and not on any scientific journal or article at -- at this point in time.
MS. LEWIS: Objection, form.
A. I'm base -- basing it on what is -- has been taught continually since -- since my training.
Q. But you're not an infectious disease expert; correct?
A. I'm not an --
Q. Okay.
A. -- infectious disease expert.
Q. And you've never studied or researched the causes of periprosthetic joint infections; correct?
A. Correct.

Page 259

Q. Okay. I mean, in fact, if airborne contamination were not an issue, the research and development of high-quality HVAC systems in operating rooms would be unnecessary; correct?
A. Well I don't know how necessary they in fact are. And the example we just discussed of laminar flow appearing to be very necessary at one point and either unnecess -- somewhere between unnecessary and hazardous at some other point, that evolution could be occurring with any of the things you mentioned.
Q. But you --
By the way, you would defer to the International Concensus with respect to the cause -- the causes of periprosthetic joint infection, International Concensus of Orthopedic Surgeons.
A. I would -- I'd want to see their commentary on that subject -- on that subject before endorsing it altogether.
Q. So you just want to take parts of what they say and then disregard other parts?
A. No. I may -- I may --
Q. Okay.
A. I may fully embrace the language that you are referencing, but I don't know that as I'm sitting here.

Page 260

Q. Well you cited -- you've --
You've had an opportunity to review their -- their -- their consensus; correct?
A. Yes.
Q. Okay. And you don't recall what they discussed with respect to --
A. Well you're asking me to subscribe to a specific statement, and I just don't think it's fair to ask me to do -- do that without it in front of me.
Q. Okay. So you -- you -- you think it's fair to take one statement out of a whole publication to support your -- your theories, but disregard the rest of the statements?
A. Well I'm not -- I'm not sure that what they say about the source of joint infections would contradict what they've said about the safety of Bair Hugger.
Q. Assuming that the Bair Hugger increases the risks of surgical-site infections, do you agree with me that that risk is not warned on the warning labels of the Bair Hugger?
MS. LEWIS: Object to form.
A. Right. And yes, I would agree --
Q. Okay.
A. -- that an unproven risk is not warned.

Page 261

Q. Are you aware that on the 200 series Bair Hugger they warned about the risk of airborne contamination?
A. Well I'm not sure what they were referring to when they said "airborne contam -- contamination." Contamination --
Q. Are you telling me that you might have a different definition of "airborne contamination" than --
A. Well contaminate -- contaminated with what?
Q. Anything. Airborne contamination.
A. I don't --
Well, so I don't know what they were -- were referring to.
Q. But when I use the term "airborne contamination" in -- in -- in -- within the --
Let me ask you this: When -- when your colleagues use the word "airborne contamination," do you know what they are referring to?
A. I'm not sure that they know what they're referring to.
Q. Oh.
A. So it could be --
You know, in my -- in my world we talk about airborne contamination of trace anesthetic gases all

the time. Is that -- is that what you're talking about, about chemical contamination? And -- and then there's a difference between particles and -- small particles, large particles, bacteria, smoke, all of these are potential airborne contaminants that we think about and talk about in the operating room setting.

Q. So if a colleague of yours is talking about airborne contam -- con -- contamination, you would need more information to know what he's talking about.

A. If they just use that phrase in a vacuum, I would need to ask for clarification.

Q. Okay.

A. But obviously, in conversation things have a context and it might be -- it might be clear.

Q. In an OR, when doctors use the term "airborne contamination," do you know what they're referring to?

MS. LEWIS: Objection, form.

A. Yeah. I don't --

I may know what they're referring to depending on the context of the conversation.

Q. You do agree that the area underneath the operating room table is not sterile.

A. Correct.

Q. Okay. And in fact doctors are -- or surgeons are taught to always keep their hands above the operating room table.

A. Surgeons are taught -- are taught that.

Q. Otherwise, you'd have to --

If -- if your hands go below the sur -- the operating room table, you'd probably have to go and -- and rescrub and -- and be sterilized and -- and, you know, rescrub; right?

A. I've seen -- I've seen that happen.

Q. All right. You've seen that happen?

A. Yes.

Q. Like the hands went underneath the table and they have to go rescrub?

A. Yes.

Q. Do they touch anything underneath the table?

A. They --

The concern -- concern was that they touched the drape under -- under the table.

Q. Are you aware that 3M markets to orthopedic surgeons use of the Bair Hugger?

A. I wasn't aware of that.

Q. Well if you're going to opine on warnings, which you are in your report, wouldn't it be helpful to know who uses the device and for what purpose and

who that -- and -- and who 3M markets the device to?

A. I'm not sure how that's relevant to an opinion on --

Did -- did you say labeling?

Q. Warnings and labeling.

A. Yeah.

Q. Given it's important to know who uses the device to determine what warnings should be --

A. I think the device --

Q. -- documented?

A. -- the devices are probably nearly universally operated and used by anesthesia staff.

Q. Well if surgeons are concerned about increased particles over the surgical site and 3M knows of this concern, and 3M also is aware that when the Bair Hugger is used it increases particles over the surgical site, do you believe there's an obligation for 3M to warn the orthopedic surgeons of the increase of particles?

MS. LEWIS: Objection to form.

A. What -- what -- what is the significance or meaning of those particles?

Q. Doesn't matter what --

A. Yes, it does.

Q. No, it --

I'm saying that the orthopedic surgeons care about particles. Whether or not it's significant to you or not, that's what the orthopedic surgeons care about, increased particles over the surgical site.

If 3M is aware of this concern by orthopedic surgeons and they're aware that the Bair Hugger increases particles over the surgical site, do they have an obligation to warn the orthopedic surgeons?

MS. LEWIS: Objection to form.

A. No, not if they know --

Q. Okay.

A. -- that the particles are inconsequential.

Q. Well how do you know the particles are inconsequential?

A. Well, because they can have the capacity to meas -- meas -- measure the output of the -- of the device.

Q. Do you -- never mind.

The 200 series warned about airborne contamination in 1987. Are you aware of that?

A. No.

Q. Okay. If that is the case, that 3M was aware of airborne contamination as of 1987, do you agree that aerosoliz -- aerosolization of bacteria that could potentially cause an infection was a known

risk for 3M?
MS. LEWIS: Objection, form.
A. No.
Q. Okay. If you yourself see, on a device that blows air, potential for airborne contamination, what would -- what would that mean to you as an anesthesiologist in the operating room?
A. I would want to know what it meant to the auth -- authors of that -- of that warning.
Q. You mean the manufacturer?
A. That is the author of the warning.
Q. Okay. But for you to get to that point, you would like to at least see the warnings so you could ask questions about it; correct?
A. Well I don't want to see warnings about things that are not genuine risks. Right? I mean I -- you know, it's like going to Cal -- going to California, "This elevator contains materials that are known to cause cancer," so I -- I --
If there is a substantial risk to the device in -- in proper use of the device, I think that is a fair -- a fair warning, but if the device produces airborne contamination that is not meaningful to my patient, then I'm not sure why I'd want to see that -- why I would want to see that warning.

Q. But you don't know either way if it's meaningful or not.
A. I'm sorry?
Q. You don't know either way unless you see a warning to even question the warning.
A. Well to some extent -- to some extent I want the manufacturer to use some judgment about what they warn me about. But if I saw the warning, I would ask questions about so what is this -- what is it contaminating the air with and what does that mean.
Q. Well you're not an infectious disease expert; correct?
A. No. But I would have some need to respond to seeing that -- seeing that warning.
Q. Are you aware that on the 510(k) application they indicated the potential of airborne contamination in the 500 series device?
A. As I said, I don't think I've seen the 510(k) applications.
Q. Okay. You haven't seen the 510(k) applications.
A. I have not seen the 510(k) applications.
Q. So you have -- you have not seen any of the internal data regarding contamination; correct?
A. Well as I said, I think the results of the

testing of the -- of -- of the filters is relevant to that -- that question, and I have seen that.
Q. Okay. And you've just recently seen it; correct?
A. Yes.
Q. You got it yesterday; right?
A. May -- within --
Within recent weeks.
Q. Okay. After you -- you -- you submitted your report.
A. Correct.
Q. Okay. But you're not a filtration expert.
A. That is -- that -- that is true.
I must say -- I must say that, unlike some of the statistics in the paper we just looked at, what I saw in that report was meaningful to me.
Q. Are you talking about the ones where they tested the -- the MERV rating, or the contamination?
A. It was --
Was it a 52.2 -- 2 test?
Q. Yeah. And that -- and that stank; right?
A. No.
Q. Fifty-two percent stank.
MS. LEWIS: Fifty-two what?
Q. Fifty-two percent stank.

A. No, I didn't say 52 percent.
Q. Oh.
A. I said the test was designated 52.2 or something like that.
Q. And of course since you did not bring this filtration document, I have no idea what you're talking about today; correct?
A. Well let me tell -- tell you that what it showed was that in the particle sizes with which I am concerned; that is, the large -- larger particles, the old and the new filters both were 99.8 percent, or thereabouts, effective in removing them.
Q. You did not bring the document today and you have no Bates numbers to refer me to the document; correct?
A. I'm not sure what the Bates -- Bates number is, but --
Q. The number that has like 3MBH at the bottom of it.
A. I -- I don't have that.
Q. Okay. Because you were told not to bring it.
A. No, I was not told not to bring -- not -- not to bring it. I was told to -- to -- to come and not to bring -- not to bring anything.

Q. You were told to what?
A. Come here and not to bring anything.
Q. Okay.
A. Which makes perfect sense because I would bring a truckload of stuff, poten -- potentially, and I have no idea what's relevant to the discussion. My expectation was -- was that if you were going to ask me about filtration, that you would have the documents relevant to that discussion.
Q. Is there anything about filtration in your report?
A. No, but you just asked me about it.
Q. Well I mean I asked you about it because you told me you could not produce a document; correct?
I can't read your mind, sir. Okay? How did I know you were going to talk about filtration? I have your report. Is there anything about your report dealing with filtration?
A. No, I don't believe there is.
Q. Okay. So how would I expect to ask you questions on filtration if it's not in your report?
A. Well many --
MS. LEWIS: Gabe, my goodness.
THE WITNESS: I'm sorry?
MS. LEWIS: Just my comment. Go ahead.

A. Because many of the allegations or suggestions of the hazards and the basis of that warning pertain directly to the efficiency of the filtration.
Q. How am I supposed to know you're going to opine on anything in filtration that's not in your expert report or in Exhibit B -- or Exhibit 2 of --
A. Well you asked -- you asked me about it.
Q. I'm talking about before today. How am I supposed to know that, sir?
A. I don't know.
MS. LEWIS: You're rising your voice unnecessarily.
MR. ASSAAD: No, I don't think it's unnecessarily about coming up with new opinions on the day before a deposition.
MS. LEWIS: He didn't come up with new opinions.
Q. Sir, how am I supposed to know that?
A. I have no idea.
Q. I mean you're a doctor. Is there any medical -- medical situation where someone could predict what someone's going to say at -- you know, at a deposition?
A. No, no. But when you ask me about warnings

about airborne contam -- contamination, that is in essence a question about filtration, and so I think that you obviously had it in your mind to discuss -- to discuss that.
Q. Well so you're now predicting what I have in my mind?
A. I'm not predicting, I'm observing what you just asked me about.
Q. The reason I brought up filtration was because you mentioned you looked at a document and you wanted to -- that wasn't part of even any of the -- the materials that --
A. No, you asked -- you asked me about the warning label -- labels before I mentioned that.
Q. Okay.
MS. LEWIS: How long have we been going now?
THE VIDEOGRAPHER: Let's see. Five hours and 23 minutes.
MS. LEWIS: I'm -- I'm sorry, I meant since the last break. I'm sorry.
MS. ZIMMERMAN: Forty minutes since the last break.
MS. LEWIS: Okay. But we're now, I'm sorry, five hours and how much?
THE VIDEOGRAPHER: And 23 minutes.

MS. LEWIS: Okay. Gabe, is this a good time for a break or --
MR. ASSAAD: Couple minutes on the warning.
BY MR. ASSAAD:
Q. The only warning that you're referring to is the hosing warning in your report; correct?
Page six.
A. Well I can -- I can -- I can read it to you, but it does comment on the hosing -- hosing warning and says -- it says that with respect to risk of contamination or infection, that I don't believe a warning -- a warning was warranted.
Q. Okay. But you're not an infectious disease expert; correct?
A. I am not an infectious disease expert.
Q. And you don't know what concerns orthopedic surgeons have with particles; do you?
A. I can't speak for orthopedic --
Q. Okay.
A. -- orthopedic surgeons.
Q. And you've never ever once in your life created any type of warning for a medical device; correct?
A. Correct.
Q. And you offer that opinion without having

seen the warnings provided on the original device, the 200 series, the 500 model, or the 700 series; correct?
A. I'm sorry?
Q. You haven't seen the warnings on any of the devices besides the 505.
A. That's probably true.
Q. Okay. You haven't looked at the operating room man -- operating manual; correct?
A. Not since -- not since they first originally put them into use.
Q. You haven't looked at any of the warnings of any other forced-air warming devices; have you?
A. I haven't seen in person any other forced-air warming devices.
Q. You haven't looked at the 510(k); have you?
A. No.
MR. ASSAAD: Okay. Let's take a break.
THE REPORTER: Off the record, please.
(Recess taken.)
BY MR. ASSAAD:
Q. Doctor, are you aware that the 1996 -- 1996 Kurz study was funded by Augustine?
A. I'm not aware of that.
Q. Would that affect your interpretation of -- or -- or your opinion of the 1996 article?

A. I -- I --
Would that affect? No.
Q. Okay. But you agree with me that in 1996 that Augustine had a final -- financial interest in the Bair Hugger.
A. I believe so.
Q. Okay. So you don't criticize him in 1996, but you criticize him -- or you criticize the authors of McGovern for having a financial interest in the subject matter.
A. I note -- I note that that is the case.
Q. So you looked at McGovern because of who had a financial interest, but you didn't look at the 1996 Kurz article.
A. I looked at the 1996 Kurz ar -- Kurz article. Are you looking about -- about the -- talking about the disclosures in partic --
Q. Yes.
A. -- in particular?
So again, I -- I may have at the time -- at the time, but I am still confident in its value.
Q. I mean we want to be objective here; right, doctor?
A. Correct.
Q. Okay. Not an -- not an advocate for either

side; correct?
A. Correct.
Q. Okay. So if you're going to criticize McGovern for some of the authors having a financial interest, you got to do the same criticisms for the Kurz for those authors having a financial interest.
Goose/gander rule; right?
A. Well I'm -- yeah. So I'm not sure what -- what "criticize" means. So fine, I recognize that Kurz was funded by Augustine and I recognize that McGovern was funded by Augustine.
Q. You believe McGovern was funded by Augustine?
A. By -- by -- by Hot Dog.
Q. Okay. Do you know if they fun -- they provided any money?
A. I don't -- I don't know. But they -- that's the --
The paper contains the disclosure.
Q. Do you know that the only thing that Dr. Augustine provided was just a Hot Dog device?
A. I don't know -- I don't know that.
Q. Okay. Were you provided Dr. McGovern's deposition?
A. It may have been among -- among the

materials I was provided.
Q. Were you provided with Dr. Reed's deposition?
A. I don't know.
Q. Were you provided Albrecht's deposition?
A. I believe I was.
Q. You --
Were you provided Legg's deposition?
A. I don't -- I don't know.
Q. Were you provided Belani's deposition?
A. I don't know.
Q. Do you know Dr. Reed was the advisor on the McGovern study, the senior doctor?
A. Do I know if he was -- if he was?
Q. Yeah. Do you know that that's the case?
A. I don't know that that's the case.
Q. Do you know that Dr. Reed has been hired by 3M to perform a study in -- in the U.K.?
A. No, I don't know that.
Q. Do you know who Nachtscheim is?
A. No.
Q. You would assume that if 3M has hired Dr. Reed to do research for them, that Dr. Reed is a competent researcher?
MS. LEWIS: Object to form.

Page 278

A. I'm unable to comm -- comment on Dr. Reed's competence as a researcher.
Q. So besides doing a literature review in your expert report, Exhibit No. 3, what methodology did you use to come up with your conclusions on pages six and seven?
A. I looked at the literature, including the systematic rev -- reviews, and my own clinical experience.
Q. Okay. I said besides the literature what did you do. Just your own clinical experience?
A. Yes. I did not undertake any primary research.
Q. So what in your clinical experience that you did to indicate that maintaining normothermia improves outcomes in surgical patients?
A. That I don't see pa -- patients often -- often shiver, that I don't see pa -- patients who are warm -- warm become dangerously hypertensive, and that I believe that the rate of surgical infect -- infections is at least at bench -- benchmark or better.
Q. Well you don't follow patients after they leave the PACU on a regular basis; do you?
A. No.

Page 279

Q. Okay. And if they did get a surgical-site infection, such as a superficial wound infection that didn't -- that didn't require surgery, that you wouldn't know about it; would you?
A. I would -- I -- I would not perhaps know about an individual patient, but in aggregate the performance of our surgical service I would be aware of.
Q. By the data.
A. By the -- by the data or by our tracking.
Q. But what have you done, I mean clinically, to show that maintaining normothermia improves the outcomes in surgical patients? What tests have you done? What data have you looked at?
A. I've looked -- looked at -- I -- I've looked -- looked at my -- my own patients and I've looked at the aggregate da -- data from our institution against various -- against various benchmarks.
Q. That could have been caused --
A reduction in infection rates could have been caused by skin prep; right?
A. It could be. All -- all of these things have many -- many cause -- many causes.
Q. It could have been caused by prophylactic

Page 280

antibiotics' timing; correct?
A. It could -- it could have.
Q. So what have you done in your clinical practice to show that maintaining normothermia improves the outcome in surgical patients?
MS. LEWIS: Objection, asked and answered.
A. As I said, the -- the --
In aggregate, I can look at the rate of surgical infections in my institution being at -- at benchmark or bett -- or better, and I look at the -- at the literature and in particular the systematic reviews.
Q. Take the literature out of it.
A. Well the literature is --
Q. Take the lit --
I'm saying in your clinical practice, what have you done to say, "Aha, maintaining normothermia reduces the incidence of surgical-site infection?"
A. I would say maintaining normother -- normothermia is one of a number of practices that lead to that, and we adhere closely enough to those practices to produce good results.
Q. If you have prophylactic antibiotics, skin prep, HVAC system, surgical procedure and technique, okay, and maintaining normothermia, and you have an

Page 281

infection rate that meets benchmark or a little bit better, how did you determine that this one, maintaining normothermia, had an effect on surgical patients -- outcomes of surgical patients and the other four --
A. I didn't say that the other four didn't.
Q. Okay. So it may -- it may or may not have an effect. You don't know; do you?
A. So on the -- on -- on the basis of my person -- of my personal exper -- experience, I have not done a study to isolate temperature management from other techniques to optimize patient outcomes.
Q. So you're solely relying on the literature to support --
A. I am principally relying on the -- on the literature.
Q. Solely relying on the literature.
MS. LEWIS: Objection, misstates the testimony.
A. No, I -- I disa -- I disagree. I look at --
If -- if our performance on infections or other important complications, cardiovascular mortal -- morbidity and -- and so forth, were outliers, then I would be looking at are we maintaining normothermia, are we giving antibiotics at

the -- and -- and -- and take it apart. So I fully recognize that these things are all multifactorial.
Q. If I ask you to give me evidence outside the literature in your clinical practice that indicates maintaining normothermia im --
A. In isolation?
Q. -- improves outcomes in surgical patients in your clinical practice, --
A. No.
Q. -- what evidence do you have?
A. If you're talking about that as the sole factor?
Q. Yes.
A. No.
Q. Okay. You have none; correct?
A. Correct.
Q. Okay. Going to page four, halfway through you write, "The opinions of plaintiffs' experts Drs. Stonnington and Jarvis largely rely on this entirely unproven relationship. In addition, these experts also attribute the alleged risk of the Bair Hugger device to the bacterial content of the internal and external surfaces of the device and the output of the Bair Hugger hose."
Did I read that correctly?

A. You read that correctly.
Q. Are those the only two criticisms -- wait, strike that. That --
Those are the only two criticisms in your report of Drs. Stonnington and Jarvis; right?
A. Well I am referencing here to this entirely unproven relationship, which is discussed in the previous sentences about laminar -- laminar flow and turbulent airflow.
Q. Okay. But my point is that those are the only criticisms of those two doctors, Stonnington and Jarvis, is in this part of the report; correct?
A. Those are the only criticisms in this -- in this re --
Q. Okay.
A. -- in this report. If you want to ask me about other statements they have made and whether I would accept or criticize them, happy to do that.
Q. You -- you had -- you had your opportunity by June 2nd to provide all your opinions, so I'm not going to ask you anything outside the report, sir. With respect to --
You haven't seen Dr. Elghabashi's report; correct?
A. Correct.

Q. Do you know what a computational fluid dynamics analysis is?
A. I've heard -- I've heard the term, but that is way -- way outside my expertise.
Q. Okay. So you would defer to a computational fluid dynamics expert with respect to computational fluid dynamics; correct?
A. Yes.
Q. So just to be clear, besides --
I mean you haven't done research on maintaining normothermia and you haven't published any articles regarding maintaining normothermia and you're not an infectious disease expert, you're not an engineer, you're not an orthopedic surgeon, so what is it with respect to your credentials that provides the appropriate methodology to determine whether or not the Bair Hugger is a safe device besides the literature?
A. "The appropriate methodology."
Q. Yes.
A. Help me understand what you mean by that.
Q. Well you're not an engineer so you can't look at the airflow of the Bair Hugger; correct?
A. Correct. I am --
Q. Okay. And you --

A. I am a clinician and I am there focus -- focusing -- thereby focusing on clinical outcomes, and that's -- that's what I am most interested in. I have been presented, through the campaign, allegations about this body of evidence on airflow or particles or something -- or something else impugning the safety of the Bair Hugger, so to the extent I am able, recognizing the limitations in my training and back -- and background, I try to -- try to make an assessment of whether those represent val -- valid indictments of the safety of the -- of the Bair Hugger. So I have not seen any one -- any one of the things that have been presented in the campaign to discredit the Bair Hugger in which even the authors represent that they have demonstrated a relationship between whatever they are reporting on and the actual risk to the patient.
MR. ASSAAD: Move to strike, non-responsive.
Q. You're not an engineer, so you can't talk about the airflow of the Bair Hugger; correct?
A. Correct.
Q. You're not an infectious disease doctor to talk about the relationship between bacterial load and periprosthetic joint infections; correct?
A. Not in -- not in detail, but I am an educated phys -- physician and so to a degree have

some familiarity with the basic principles, but I am not a specialist in that area.
Q. Well you've never done any studies with respect to bacterial load and --
A. No. You --
Q. -- periprosthetic joint infections.
A. No, but I --
Q. I mean I could -- I could read a study as well. I mean I could read --
A. No, but you -- you --
Q. But let's talk about your experience.
A. But you haven't, you know, written consult -- consultations on patients with infectious disease -- disease problems as a student or a -- or -- or a trainee.
Q. And you consult with an I.D. expert.
A. I was under the supervision of a faculty I. -- I.D. expert, so I learned something about infectious disease. I'm not an infectious disease ex -- expert.
Q. Okay. That's all I'm saying.
A. Okay. I have conceded that --
Q. You've done no studies --
A. -- half a dozen times today.
Q. You've never done any studies on bacterial

load and periprosthetic joint infections.
A. I have not done any studies --
Q. Okay.
A. -- on that.
Q. Okay. You have never --
You're not an aerobiologist; correct?
Correct?
A. I'm not a --
Q. Aerobiologist.
A. I am not an aerobiologist.
Q. You're not a microbiologist; correct?
You're an anesthesiologist.
A. Correct.
Q. Okay. And you use the device to -- Bair Hugger to maintain normothermia; correct?
A. Correct.
Q. Okay. But I'm talking about whether or not the Bair Hugger -- the Bair Hugger --
I'm not talking about the literature. Okay?
No literature here.
A. Well --
Q. What is it about your credentials that would indicate that the Bair Hugger, okay, does not cause an increased amount -- or increase the bacterial loads over the surgical site? Credentials, not literature.

A. My credentials have no -- say nothing -- say nothing about the bacterial load. I'm not sure how my credentials could say anything about the bacterial load or --
Q. I'm just asking. So you agree with me that there's nothing --
A. My creden -- my credentials say something --
Q. Your experience. Experience, education, training.
A. Okay.
Q. What about your experience, education, training, about you, doctor, gives you the expertise to determine whether or not the Bair Hugger has any effect on the airflow that could increase the bacterial load over the surgical site?
MS. LEWIS: Asked and answered.
A. I have said multiple times that I am not an expert in bacterial load over the -- over the surgical site.
Q. So I'm just trying to figure out --
Forget about the literature. Without the literature, you actually have no methodology to offer the opinion that the Bair Hugger does not increase the bacterial load over the surgical site and is safe.
MS. LEWIS: Objection, form.

A. Without the literature.
Q. Without the literature.
A. That's -- that's -- that's corr -- correct. I've already said that.
MR. ASSAAD: Okay. That's all I have. Thank you.
MS. LEWIS: We'll switch place -- places.
THE REPORTER: Off the record, please.
(Discussion off the record.)
REDIRECT EXAMINATION
BY MS. LEWIS:
Q. Dr. Hannenberg, you were asked questions about a study called Darouiche and you mentioned that you had not seen that study and that study wasn't presented for you to review today; correct?
A. That is correct.
Q. Did Mr. Assaad mention to you that -- in that study, whether the Bair Hugger was even studied in that study?
A. I think he said that the Bair Hugger increased bacterial load and infections.
Q. But did he tell you --
MR. ASSAAD: Objection, misstates.
Q. But did he tell you that the Bair Hugger was even tested in that study? I mean do you even know if

it was tested in that study or not?
A. No.
Q. You were asked earlier to put an S next to all the articles that you cited in Exhibit 2, which is titled "Materials Considered;" correct?
A. Yes.
Q. And this is the one that was presented this morning; correct?
A. Yes.
Q. And you put an S next to -- tell me if this is right -- the ECRI Institute. Did you put an S next to that one?
A. Yes, I did.
Q. Did you put an S -- S next to the Centers for Medicare & Medicaid Services, number two?
A. Yes, I did.
Q. Okay. Although they're not officially numbered, I'm going to sort of say -- try as best to --
A. Okay.
Q. -- identify them.
You put an S next to the Hooper study?
A. Yes.
Q. Next to a website. Are you -- I guess it's the NICE --

A. Yes, it is.
Q. -- organization; correct?
A. Yes.
Q. You put an S next to Miller's Anesthesia; correct?
A. Yes.
Q. An S next to the Kurz and Frisch study; correct?
A. Correct.
Q. An S next to the Avidan study.
A. Yes.
Q. An S next to the Memarzadeh study; correct?
A. Yes.
Q. An S next to the Proceedings of the International Concensus Meeting on Periprosthetic Joint Infection; correct?
A. Yes.
Q. An S next to Melling and Leitjens, those two studies?
A. Yes.
Q. You put an S next to the Scott study.
A. Yes.
Q. Okay. And then last you put an S next to the Association of Perioperative Registered Nurses.
A. Yes.

Q. The "Perioperative Standards and Recommended Practices."
A. Yes.
Q. You were also asked questions about the Avidan study, in particular whether you believed the Avidan was a good study; correct? You remember that questioning?
A. Yes.
Q. And whether you thought the study was underpowered or not. And so you remember that sort of line of questioning?
A. Yes.
Q. Why did you put an S next to Avidan at the -- on the -- I un --
As I understand, the S stood for you thought that study supported your opinions, correct, --
A. That is correct.
Q. -- that the Bair Hugger was safe?
A. That -- that is correct.
Q. Why did you say that --
Why do you say that the Avidan study supports your opinion?
A. Because it specifically add -- addresses the bacterial output of the Bair Hugger blan -- blanket and it stands apart from other -- other studies that

look at the internal contents of the heat generator or even the hose itself, and I think that the -- in clinical use what is most important is what is in the air that is being delivered to the patient, which is through the blanket, and the fact that they were unable in multiple iterations of trial -- of trials with that to produce any bacterial growth seems highly persuasive to me to counteract any argument that the Bair Hugger blanket is delivering bacteria into the operating room environment.
Q. So the --
One of the findings of the Avidan study was that when the blanket was applied, which is the way it is used -- you use it in the OR, Avidan did not find any bacterial growth; is that correct?
A. That is correct.
Q. Is Avidan a study that shows that the Bair Hugger does not increase bacteria to the patient?
MR. ASSAAD: Objection to form.
A. That -- that is a conclusion I would -- I would draw from the Avidan -- Avidan study.
Q. You've been asked lots of questions about your methodology and you've described various methodologies that you've used. Can you --
Well let me ask this question: Did you rely

Page 294

on your background and educational training in reaching the conclusions that you did in your expert report?
MR. ASSAAD: Objection to form.
A. Yes. Yes, I did.
Q. Did you rely on your clinical experience, the years of clinical experience that you've worked with the Bair Hugger, in reaching the conclusions that you have in your expert report?
MR. ASSAAD: Objection to form.
A. Yes. Yes.
Q. You've already testified quite a bit about the literature that you reviewed in reaching your opinions; correct?
A. Yes.
Q. And some of those articles are listed in both Exhibit 2, which is the Materials Considered, and the references that are in Exhibit 3, which is your report; correct?
A. Yes.
MR. ASSAAD: Objection to form.
MS. LEWIS: Thanks, doctor.
THE WITNESS: Thank you.
MR. ASSAAD: I might have a few follow-up questions.

Page 295

MS. LEWIS: Want to move up?
MR. ASSAAD: Maybe. We'll see.
THE REPORTER: Off the record, please.
(Discussion off the record.)
RECROSS-EXAMINATION
BY MR. ASSAAD:
Q. Doctor, you cite the Memarzadeh study in Exhibit 2; correct?
A. Yes.
Q. If you could --
You think that's a study that you cite?
A. I said I -- I -- I cited it because it was a state -- a statement, if I recall correctly, from National Institutes of Health's assessment on this question of safe -- safety of the forced-air warming.
Q. You think it was a statement?
A. There was a statement in -- in there that the technology was safe.
Q. So you think it was a statement, that's my question, by the NIH.
A. It was --
Again, I'm happy to -- happy to look at it to verify.
Q. It's your report, doctor. Do you know what it is? Is it a statement, is it a study, do you know?

Page 296

A. It's the report of a process at the NIH assessing -- assessing this question, and the conclusion was that it was a safe practice.
Q. It wasn't a study and it wasn't a statement, it was a letter to the editor from the Moretti study. Are -- are you aware of that?
Do you know what the Moretti study is?
A. Again, sounds -- it -- it sounds familiar, but I don't know the details as we sit here.
Q. I mean you're -- you're getting paid $500 an hour to look at documents; correct?
A. Correct.
Q. And you got paid $2,000 just for the first hour of today's deposition; correct?
A. Correct.
Q. And $200 each every other -- every other hour; correct?
A. Correct.
Q. And you wrote this report; correct?
A. Correct.
Q. And you looked at the articles; correct?
A. Correct.
Q. And you can't tell me whether or not Memarzadeh is a study, a statement, or a letter to the editor?

Page 297

A. I -- I read it some time -- some time ago and I need to refresh my memory.
Q. You prepared for today's deposition; correct?
A. Yes.
Q. You spent about 15 hours in preparation of today's deposition.
A. Well if you say -- if you say.
Q. Well that's what -- that's what you said. You approximated 15 hours since June 15th and today in preparation of today's deposition.
A. Okay.
Q. How did you prepare? Did you look at the studies in preparation?
A. I looked at -- I looked at some of the studies. I did not look -- apparently look at all of the studies.
Q. Okay. Did you look at the underlying CFD analysis Memarzadeh did that -- in that letter to the editor?
A. In most of these instances, as I -- as I've said, my expertise in statistical analysis and methodologic design puts me in a position where I re -- rely on methodol -- methodologists and -- and editorial boards.

Q. So you're relying on Memarzadeh on a CFD study that you don't even understand; isn't that correct?
A. I am relying on the conclu -- the conclusion that he and -- he drew.
Q. But you're not an engineer. You don't understand the methodology he used, do you, to come to that conclusion? Do you?
A. Well if he is rep -- repre --
Q. "Yes" or "no." Do you understand the CFD analysis?
MS. LEWIS: Stop interrupting him, Gabe.
Q. "Yes" or "no."
A. Do I --
No. That is not my expertise, --
Q. Do you know what the Navier-Stokes equations are?
A. -- that's correct.
Q. Do you know what the Navier-Stokes equations are?
A. No, I don't.
Q. Okay. So you just take the conclusions of Memarzadeh without even understanding how he got to his conclusions; do you? Isn't that correct?
A. Correct.

Q. Okay. Did you --
Are you aware that in that letter to the editor he actually indicates that forced-air warming slightly disrupts laminar flow?
A. The conclusion of interest is whether it is safe -- safe or not, as I've said multiple times. Its impact on lam -- laminar flow is at best tangential to the question.
Q. So again you're just picking and choosing statements that you like and disregarding statements that don't like; correct?
MS. LEWIS: Objection, argumentative, --
A. I -- I wouldn't say that.
MS. LEWIS: -- misstates his testimony.
Q. Were you aware that in the Memarzadeh letter to the editor and the study he found that the 505 disrupted laminar flow? Are you aware of that? "Yes" or "no."
MS. LEWIS: Objection, form.
A. I -- I have said I don't believe that the discussion of laminar flow informs my opinion about the safety of the Bair Hugger.
Q. Can you please answer my question. Were you aware that in the study he said the 505 disrupted laminar flow?

MS. LEWIS: Same objection.
A. I may have at the time of the initial rev -- review.
Q. Do you know the difference between the 505 and the 750?
A. No.
Q. Do you know what blanket was used in Memarzadeh's study?
A. No.
Q. It was an upper body blanket; wasn't it?
A. If you say so.
Q. Well do you know?
A. I just said I didn't.
Q. Okay. So you just want to draw on a conclusion of a study that you like without knowing what the device -- what device was used, what blanket was used, and the engineering principles behind the study. Is that a fair testament of your -- of -- of your -- of your take of the Memarzadeh study?
A. Well the conclusions that Memarzadeh communica -- communicated were subject to editorial review and come with the imprimatur of the National Institutes of Health. I find that that's per -- persuasive.
Q. Where did you get that information from,

sir? It's a letter to the editor, it's not peer-reviewed.
A. It's reviewed -- it's reviewed by the editors.
Q. Yeah. But it's not peer-reviewed. It's not peer-reviewed the same --
Do you know what peer review is?
A. I know -- I have been a peer reviewer, I know very well what -- what it is. But not every letter to -- that's sent to a journal is published. There is a less-intens -- intensive review process about which letters get published and which don't, and this satisfied the editors of the journal.
Q. But it's not peer-reviewed; correct?
A. Normally it is not.
Q. Okay. Do you know -- do you know whether or not Memarzadeh used draping in his CFD analysis?
A. I don't know the details --
Q. Okay.
A. -- of the Memarzadeh study.
Q. So you were provided that paper by defense counsel, you just cited to it because it sounds good.
A. I don't know whether --
Q. Got it.
A. -- it was provided or I found it in my own

literature search.
Q. Let's talk about ECRI. You reviewed -- you reviewed the ECRI article, correct, the literature review?
A. Yes.
Q. Is there one statement in ECRI that says the Bair Hugger is a safe device?
A. Verbatim?
Q. Even if it comes close.
A. Yes. The conclusion of EC -- EC -- ECRI is that it is -- it is safe to use.
Q. It says, "Consequently, ECRI Institute does not believe that the currently available evidence justifies discontinuing the use of forced-air warming during surgery."
You interpret that as saying the Bair Hugger is safe?
A. Yes.
Q. You do?
A. Yes, I do.
Q. So then if it's safe, why do they say, "We will continue to monitor this topic through the published literature and will update our recommendation as warranted?"
A. New evidence may become avail -- available.

Q. No. They're just saying there's not enough evidence at this point in time.
A. No, they did --
Q. Okay.
A. -- they did not say that.
Q. Okay. International Concensus says further research is warranted. Are you aware of that?
A. Yes.
Q. Okay. ECRI says they're going to monitor it; correct?
A. Yes.
Q. Okay.
(Discussion off the stenographic record.)
Q. Do you even acknowledge there's a theoretical risk that the Bair Hugger can cause a surgical-site infection?
MS. LEWIS: Objection to form.
A. I know no basis for that theory.
Q. So even though the International Concensus has a basis for that statement, you have no basis.
A. I --
Correct, I have no -- I have no basis.
MR. ASSAAD: That's all I have.
THE REPORTER: Anything further?
MS. LEWIS: No.

THE REPORTER: Off the record, please.
(Deposition concluded.)

C E R T I F I C A T E

I, Richard G. Stirewalt, hereby certify that I am qualified as a verbatim shorthand reporter, that I took in stenographic shorthand the deposition of ALEXANDER A. HANNENBERG at the time and place aforesaid, and that the foregoing transcript is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Deerwood, Minnesota, this 14th day of August, 2017.

RICHARD G. STIREWALT
Registered Professional Reporter
Notary Public

C E R T I F I C A T E

I, ALEXANDER A. HANNENBERG, hereby certify that I have carefully read the foregoing transcript, and that the same is a true and complete, full and correct transcription of my deposition, except:

PAGE/LINE	CHANGE	REASON

ALEXANDER A. HANNENBERG
Deponent

Signed and sworn to before me this ____ day of September, 2017.

_____
Notary Public